Problem Formulation Documents - Public Comments

FULL LIST OF COMMENTS

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#	Submitter	Attachments (#)	Category (RegNex, Editorial, Exposure, Fate, Engineering, Human Health, Eco Health, PESS, Policy, Other, Systematic Review, General)	Document Section #	Comment	Applies to ALL (Y/N)	1-BP	1,4-Dioxane	PERC	PV29	HBCD	CCl4	DCM	NMP	TCE	Asbestos	RAD POC	Docket #	Action Needed
1	ACC	3	General	N/A	Section 26 of TSCA mandates that EPA make science-based decisions under Sections 4, 5, and 6 of TSCA in a manner consistent with the best available science and the weight of the scientific evidence. EPA's development of a structured process to identify, evaluate, and integrate evidence from both the hazard and exposure assessments developed during the TSCA risk evaluations is appropriate and will provide increased transparency into the TSCA risk evaluation process.	Y	N	N	N	N	N	N	N	N	N	N			
2	ACC	3	General	N/A	In general, EPA should make the results of its systematic review process available as part of the docket for each risk evaluation, including its selection of key studies and study quality evaluations.	Y	N	N	N	N	N	N	N	N	N	N			
3	ACC	3	General	N/A	EPA has identified those conditions of use that will be within the scope of the risk evaluations, as well as those that will be excluded. The risk evaluation rule makes clear that EPA should focus on those conditions of use that raise the greatest potential for risk. ACC generally supports the approach taken to addressing conditions of use within each of the 10 problem formulations. This approach allows EPA to be efficient, while still addressing the highest priority conditions of use that pose the greatest potential risk.	Y	N	N	N	N	N	N	N	N	N	N			
4	ACC	3	General	N/A	The problem formulation documents present a thoughtful approach to identifying current uses that are appropriate for inclusion within the scope of the risk evaluation. We also appreciate EPA's efforts to explain why the conditions of use that are not within scope will be excluded. ACC encourages continued stakeholder engagement with manufacturers and users of these chemicals throughout the risk evaluation process to ensure the best available information is used.	Y	N	N	N	N	N	N	N	N	N	N			
5	ACC	3	General	N/A	As EPA gains more experience conducting TSCA risk evaluations for high priority chemicals, it would be useful if the Agency would develop a framework that articulates its process for deciding when conditions of use are in or out of scope. This would help EPA streamline future efforts, provide greater public understanding of EPA's decisions, increase transparency and reproducibility, and enable industry to identify the types of information that may be most helpful for manufacturers, processors, and downstream users to develop and/or share with EPA. Developing a framework would also help industry anticipate which conditions of use will be the likely focus in future assessments so that they can direct resources efficiently to develop and/or gather information relevant to EPA's potential risk evaluations and facilitate proactive data collection efforts.	Y	N	N	N	N	N	N	N	N	N	N			
6	ACC	3	General	N/A	"Section 9(d) of TSCA imposes a general requirement on EPA to consult and coordinate with other federal agencies for purposes of "achieving the maximum enforcement" of TSCA while imposing the "least burdens of duplicative requirements on those [subject to TSCA]." This Section 9(d) coordination requirement has existed since TSCA was originally enacted and was unchanged by the 2016 amendments. Section 9(d) is a general policy directive that applies to EPA for all TSCA implementation activities. The risk evaluation rule also contains a general consultation provision that codifies the statutory requirement for interagency collaboration during the risk evaluation process." The principle driving this coordination requirement is that EPA should avoid imposing unnecessary or duplicative burdens on regulated entities and avoid regulatory actions best taken by another agency or under other EPA authority. This necessarily includes all manner of Agency interaction with regulated entities, including submission of information, docket management, responses to comments, and other engagement with multiple regulatory bodies. Where non-TSCA regulatory schemes are sufficiently effective at addressing risk, EPA may properly exclude covered conditions of use from the scope of the risk evaluation.	Y	N	N	N	N	N	N	N	N	N	N			
7	ACC	3	Exposure	N/A	Regarding occupational exposures, EPA should consult early with OSHA in the risk evaluation process—certainly at the earliest stages of the risk evaluation and well before the scope is released. This consultation should continue throughout the risk evaluation. None of the 10 problem formulations make clear what consultation may have occurred, or when it occurred. Although the problem formulations do identify available occupational exposure levels (OELs), i.e., PELs, TLVs, and IDLH values, additional information should be provided regarding the factors EPA will take into consideration when evaluating OELs. For example, consideration should be given to whether the OEL includes current toxicological and epidemiological data to support the development of the threshold limit value. EPA also presents summarized personal monitoring air samples obtained from OSHA inspections, but it is not clear how these data were obtained from OSHA and under what circumstances the data were gathered.	Y	N	N	N	N	N	N	N	N	N	N			
8	ACC	3	Exposure	N/A	EPA should give preference to direct data obtained for uses being evaluated with consideration given to how the data were gathered (i.e., workplace exposure monitoring data are gathered on a more routine basis while OSHA monitoring is conducted typically in compliance with the OSHA Technical Manual for 8 hours and the sample will generally involve the scenario or tasks in which the highest exposure is expected).	Y	N	N	N	N	N	N	N	N	N	N			
9	ACC	3	General	N/A	For purposes of 9(d) compliance, it would be helpful if subsequent risk evaluation scopes offer more detail regarding EPA's coordination with other agencies, including information such as consultation plans, data shared, etc. We encourage EPA to include such a coordination plan in future scopes and to include these plans in the draft risk evaluations, including notations where consultation has occurred.	Y	N	N	N	N	N	N	N	N	N	N			
10	ACC	3	Exposure	N/A	It would be helpful for EPA to describe the decision criteria/framework by which it will evaluate whether to include occupational exposures in the scope of a risk evaluation. This description was not included in the 10 problem formulation documents.	Y	N	N	N	N	N	N	N	N	N	N			
11	ACC	3	General	N/A	EPA should apply a tiered approach throughout the risk evaluation process–from screening/prioritizing chemicals to conducting risk evaluations–under amended TSCA. This is essential to enable EPA to meet TSCA's statutory deadlines for completing risk evaluations, adhere to TSCA's robust scientific standards, and enable both EPA and the regulated community to apply limited resources efficiently.	Y	N	N	N	N	N	N	N	N	N	N			
12	ACC	3	General	N/A	When a screening-level assessment is insufficient to conclude a lack of risk to exposed populations, EPA should take steps to refine the risk evaluation allowing more accurate quantification of potential risks. The scoping/problem formulation documents indicate where the EPA feels it has sufficient information and where additional information and use of higher-tier tools is warranted. In situations where EPA may need to perform higher-tier assessments for the risk evaluation, more information is needed on the types of data and techniques that EPA will utilize. For example, EPA should indicate how probabilistic risk assessment (PRA), uncertainty analyses, and the use of statistical tools such as Bayesian statistics would be used at a higher tier within the overall problem formulation framework. A tiered, iterative approach is critical to the production of high quality risk evaluations based on the best available information.	Y	N	N	N	N	N	N	N	N	N	N			

13	ACC		3	Exposure	N/A	The value of tiered exposure assessment is well-established. In its 1992 guidelines on exposure assessment,10 EPA discusses the value of tiered exposure assessments from screening-level assessments to more complex assessments. This perspective was reiterated in EPA's 2016 peer review draft update of the 1992 guidelines. The 2016 draft update included specific discussion of considerations in tiered assessments, as well as the notion of "fit for purpose" assessments, stating "[t]he type and purpose of an exposure assessment determine the data and information requirements." The EPA Office of Research and Development (ORD) ExpoBox tool box for exposure assessors identifies exposure assessments tools by tier and type, both screening-level and refined, for planning, scoping, and problem formulation. The purpose of tiered exposure approaches is well understood: to identify uses of chemicals that, under very conservative (e.g., maximum) exposure assessment assumptions, are not likely to pose a health risk. Depending on the conditions of use, the exposure assessment information can be used either to identify a chemical as a low priority or to be factored into the overall risk evaluation. Exposures that initially exceed hazard benchmarks in Tier-1 exposure assessments would require more refined, higher-tiered approaches to exposure assessments. This would include the application of more realistic parameters related to the likely duration, intensity, frequency, and number of exposures and more realistic exposure scenarios to more accurately quantify actual risks of the chemical. The importance of EPA using a tiered approach to exposure assessment in its TSCA risk evaluations cannot be overstated. A tiered approach allows for both a more rapid, yet systematic, approach for assessing conditions of use in a first-tier screen, so that resources are used effectively when a refined exposure assessment is necessary for those conditions of use that do not "pass" a first-tier screen. well-defined, tiered exposure approach can lead to greater efficiencies in chemical risk evaluations under TSCA. Congress clearly valued such efficiency highly as evidenced by the aggressive deadlines it set for EPA to conduct TSCA risk evaluations. Congress also directed the Agency to consider the likely duration, intensity, frequency, and number of exposures under the conditions of use.	Y	N	N	N	N	N	N	N	N	N	N			
14	ACC		3	Exposure	N/A	The value of tiered exposure approaches in risk evaluations is even broader than exposure assessment. This was discussed in the Health and Environmental Sciences Institute's (HESI) Coordinated Risk Assessment in the 21st Century (Risk21) project. A review article published in 2014 discussing Risk21's principles and framework for decision-making in human health risk assessment emphasizes that problem formulation for risk assessment should not be a hazard-driven process, but instead should start with exposure, focusing on exposure scenarios of greatest concern integrated with hazard information to support risk-based decision making. The article suggests this approach would result in an early estimate of potential human exposure in relevant populations, including susceptible populations, which would characterize the degree of specific toxicological data needs. The Risk21 framework also addresses two other principles: (1) additional data should be acquired "only if necessary and when they add value" and (2) flexibility, "such that a higher tier hazard assessment approach can be coupled with a lower tier exposure approach, and vice versa." Considerable progress has been made over the last several years in developing screening-level exposure prediction models for chemicals in commerce. These approaches can be of particular utility in conducting Tier-1 assessments for many chemicals. In the context of TSCA's risk evaluations, tiered-assessment concepts equip EPA with the tools it needs to meet TSCA's aggressive deadlines for completing risk evaluations of high priority chemicals. Tiered assessments also enable EPA to apply limited resources in an efficient manner. Using a clear, science-based tiered-assessment approach, EPA and the regulated community can perform exposure assessments in TSCA risk evaluations, enabling efficient decision-making.	Y	N	N	N	N	N	N	N	N	N	N			
15	ACC		3	Exposure	N/A	The draft problem formulation documents of the initial 10 chemicals mention the Agency's plans to use tiered exposure assessments in its risk evaluations of these chemicals, but the documents lack specifics. A clear "road map" showing EPA's approach to tiered exposure assessments is needed in EPA's scoping documents. Such a road map—or decision tree—would provide structure to EPA's approach to exposure assessments under TSCA. This structure would also be useful to explain how EPA will integrate the results of its tiered exposure assessments with the results from its tiered-hazard assessments in TSCA risk evaluations. A road map would signal to the regulated community the type of reasonably available exposure information EPA plans to rely upon, what additional exposure information might be needed, and what actions manufacturers could take early in the risk evaluation process to provide EPA the needed exposure information. EPA should delineate what kinds of data and information it could accept to refine lower-tier exposure assessments.	Y	N	N	N	N	N	N	N	N	N	N			
16	ACC		3	Exposure	N/A	Specifically, with respect to potential human exposures in the problem formulation documents, EPA should identify: -The screening-level exposure information/models EPA will use to address human exposure in Tier-1 exposure assessments; -The approach to hazard characterization and threshold EPA will use to ascertain the need for a higher-tier exposure assessment; -How EPA will communicate Tier-1 exposure screening-level results; -The higher-tiered information and models EPA will use to address human exposures, suggested by the results of the screening-level information/models; -How EPA might use tiered exposure evaluations for specific exposure scenarios (e.g., occupational, consumer, residential, etc.); -What kind of data and information EPA would accept (i.e. from stakeholders) to refine a Tier-1 screening exposure assessment.	Y	N	N	N	N	N	N	N	N	N	N			
17	ACC		3	Exposure	N/A	TSCA Section 26(l) requires EPA to develop "policies, procedures and guidance that the Administrator determines are necessary to carry out the amendments" of amended TSCA. EPA indicates its intent to use tiered approaches in TSCA risk evaluations, but guidance is needed. EPA should develop new, more specific guidance on its plans to use tiered approaches to exposure assessment in TSCA risk evaluations. In doing so, EPA must move beyond mere "concepts" and reference lists to specific information, models, and tools. As stated earlier, EPA should indicate how PRA, uncertainty analyses, and the use of statistical tools would be integrated as a higher tier assessment. Specific and transparent guidance is needed to understand how the Agency will conduct its exposure assessments so that manufacturers can provide the most relevant information early on in the process to the Agency and so that stakeholders understand the process. As stated earlier, EPA should indicate how PRA, uncertainty analyses, and the use of statistical tools would be integrated as a higher tier assessment. Such guidance will also allow stakeholders to provide additional information to refine initial lower tier exposure estimates. Further program-specific guidance is also needed for those manufacturers that plan to conduct risk evaluations for EPA's consideration and must conform to EPA's approach to risk evaluations should they do so. Guidance on tiered approaches will help streamline the risk evaluation process under TSCA and enable EPA to meet TSCA's new mandates.	Y	N	N	N	N	N	N	N	N	N	N			
18	ACC		3	Exposure	N/A	Canada's Chemical Management Plan (CMP), Australia's Inventory of Chemical Substances,23 and the EU's Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) program24 employ tiered approaches in their exposure assessment approaches for chemicals. EPA should review those approaches to ascertain their usefulness in new EPA guidance on tiered exposure assessments in TSCA risk evaluations.	Y	N	N	N	N	N	N	N	N	N	N			
19	ACC		3	Exposure	N/A	According to EPA's problem formulations, EPA plans to further analyze occupational exposures in nine of the 10 chemicals risk evaluations. EPA must be more transparent about its coordination with OSHA regarding its plans to address occupational exposure issues in TSCA Section 6 risk evaluations. The methods, models, and databases that the Agency uses to conduct its occupational exposure assessments must be adequate to satisfy TSCA's Section 26 standards for best available science and weight of the scientific evidence. EPA should be more transparent about the OSHA and NIOSH databases that EPA plans to rely upon in these risk evaluations. Greater transparency will provide manufacturers notice about the type of information EPA may not have, but may need, to conduct a realistic occupational exposure assessment.	Y	N	N	N	N	N	N	N	N	N	N			

20	ACC	3	Exposure	N/A	In eight of the problem formulation documents, EPA has identified OSHA's Chemical Exposure Health Data (CEHD) and NIOSH's Health Hazard Evaluation (HHE) program data as two major sources of occupational monitoring data that it will rely upon in the risk evaluations. However, EPA does not discuss what information in these databases it plans to rely upon; how representative the data are; what criteria EPA will use in deciding which data are or are not applicable for its exposure assessments; or how it plans to assess those data in the context of current OSHA regulations and industrial hygiene practices. EPA must provide greater detail about its use of the information in these OSHA and NIOSH databases to enable stakeholders to comment upon the data quality for the purposes for which EPA plans to rely upon the data, and to provide the Agency higher quality data where it exists.	Y	N	N	N	N	N	N	N	N	N	N			
21	ACC	3	Exposure	N/A	For instance, it is our understanding that the OSHA CEHD information does not include a description of the activities associated with the specific exposure measurements. Without this information, how will EPA be able to apply these results to the conditions of use identified for a chemical? Absent sufficient knowledge of activities associated with occupational exposure measurements, EPA might very well improperly assign exposure values to a certain condition of use/application. This could result in inappropriate conclusions about risk under specific conditions of use or risk management recommendations for protection of workers. It appears that this database reports non-detects (ND), but it does not specify the limit of detection (LOD). Without an understanding of the accuracy of the data, how will EPA use this data to inform estimates of exposure? In occupational settings, potentially hazardous exposures are eliminated or minimized by the use of training, industrial hygiene programs, engineering controls, closed systems, personal protective equipment (PPE), labeling, medical surveillance, etc. Over the past several decades, these engineering and industrial hygiene practices have continually improved. For example, as part of ACC's Responsible Care® Program, ACC member companies must implement ACC's Process Safety Code, which aims to supplement existing process safety requirements contained within the Responsible Care Management System® and RC14001® technical specifications. The Process Safety Code is intended to complement regulatory standards that, by necessity, focus on process safety at an individual facility. Another concern with the OSHA CEHD database is that much of the data were developed during inspections of facilities suspected of having high employee exposures. This suggests these data are not representative of occupational exposures from facilities that are in compliance with OSHA standards. EPA should address this fact in its quality review of the data/information underpinning its risk evaluations.	Y	N	N	N	N	N	N	N	N	N	N			
22	ACC	3	Exposure	N/A	ACC understands that some ACC members have provided EPA with occupational monitoring information for use by the Agency in problem formulations for some of the initial 10 chemicals, but this information was apparently not reflected in the problem formulations issued on June 11, 2018. EPA should be clear in the draft risk evaluations how such submitted occupational monitoring information was used to prepare the problem formulations and considered in the risk evaluation.	Y	N	N	N	N	N	N	N	N	N	N			
23	ACC	3	Exposure	N/A	EPA indicates it plans to further analyze occupational exposures in the draft risk evaluations in nine of the 10 problem formulations. EPA has conducted very few worker exposure assessments on existing TSCA chemicals in the past and its Exposure Factors Handbook does not address occupational exposures.EPA has occupational exposure tools that are designed for specific purposes. For example, ChemSTEER was developed as a conservative screening tool used to estimate workplace exposures and environmental releases for new chemicals that are manufactured and used in industrial/commercial settings. However, broad guidance is not currently available for evaluating occupational exposures under TSCA, in particular with respect to the evaluation of existing chemicals. EPA should develop new guidance for evaluating occupational exposures under TSCA. To develop this guidance, EPA should certainly consider its own information, models, and tools on occupational exposure. EPA should also update some of its older tools and methods to evaluate worker exposure. EPA should update its 1997 Generic Scenarios for industry-specific workplace release and exposure estimation to make certain they reflect current industry practice. Many industrial practices in use today go beyond the legal regulatory requirements of OSHA. EPA should consider current industrial hygiene practices as part of the conditions of use of manufacturing. Additional Generic Scenarios may need to be developed to cover conditions of use for which Generic Scenarios do not currently exist.	Y	N	N	N	N	N	N	N	N	N	N			
24	ACC	3	Exposure	N/A	It is also critical that EPA consider other information and tools available from OSHA, from the American Industrial Hygiene Association (AIHA), and from other jurisdictions to develop new occupational exposure guidance for TSCA purposes. EPA should consider the applicability of new models being used in Canada and the EU in their chemical regulatory programs. In considering information and tools from OSHA, AIHA, and other jurisdictions, EPA should also consider the adequacy and appropriateness of use of those tools in the TSCA context.	Y	N	N	N	N	N	N	N	N	N	N			
25	ACC	3	Exposure	N/A	With respect to dermal exposures, the problem formulation documents identify several models for application to four of the 10 chemicals. EPA's existing dermal exposure assessment guidance is primarily geared toward neat compounds in soil or water, and it is not clear whether this guidance is sufficient to evaluate chemicals encountered in industrial-use scenarios.	Y	N	N	N	N	N	N	N	N	N	N			
26	ACC	3	Exposure	N/A	For inhalation exposures, EPA has identified several models it plans to use in nine of the problem formulations. EPA guidance on potential inhalation exposures in occupational conditions of use under TSCA would be helpful.	Y	N	N	N	N	N	N	N	N	N	N			
27	ACC	3	Exposure	N/A	Guidance on occupational exposure assessment under TSCA should address how the Agency will consider standard industrial hygiene practices as well as how that information will be incorporated into its exposure assessments and how ultimately that information will be integrated into the risk evaluation. EPA should address and identify the specific information the Agency will need to accomplish these steps; the level of detail needed to enable the Agency to reach a determination about the adequacy of design measures such as: closed systems; the use of engineering controls and labeling requirements (e.g., the use of gloves or other PPE); and other operating procedures and management practices currently in use to eliminate or adequately minimize exposures in occupational settings. EPA should describe how these considerations are incorporated into a tiered occupational exposure assessment.	Y	N	N	N	N	N	N	N	N	N	N			
28	ACC	3	Exposure	N/A	EPA may need to gather information from industry regarding current occupational exposure protection practices. Industry may be able to facilitate access to that information. Manufacturers and organizations like AIHA may be able to help the Agency gather information about exposure data in occupational settings and industrial hygiene practices in various workplace situations. Ultimately, through such efforts, an EPA exposure factors handbook for occupational exposures could potentially be developed to address TSCA risk evaluation needs.	Y	N	N	N	N	N	N	N	N	N	N			
29	ACC	3	Exposure	N/A	Consistent with application of a tiered approach to assessing exposure, EPA should articulate what kind of data will be acceptable to refine an initial lower tier occupational exposure assessment. For example, if a screening level estimate from ChemSTEER needs to be refined, a road map (as described above) would be a key element of guidance to develop the necessary information to conduct a higher tier assessment.	Y	N	N	N	N	N	N	N	N	N	N			
30	ACC	3	Exposure	N/A	EPA should be more transparent about specific exposure models, margins of exposure and occupational exposure limits that it intends to utilize during the risk evaluation process. This will allow stakeholders to provide the Agency the exposure information it needs and can lead to better understanding as to how EPA will make risk determinations.	Y	N	N	N	N	N	N	N	N	N	N			
31	ACC	3	Exposure	N/A	ACC agrees with EPA's support for using tiered approaches generally, and in exposure modeling in particular. Under a tiered, iterative approach, screening-level tools, which are "protective by design," may be used initially. For substances that appear to present potential risks following a screening-level assessment, EPA should then proceed to use higher-tier tools. By beginning with screening-level assessments—which use more conservative assumptions and information than higher tier models—the Agency can optimize resource allocation by identifying exposure routes that present less risk early in the assessment process. When a Tier-1 screening assessment indicates low risk for a particular condition of use, the Agency should have a high degree of confidence that the potential risks are lower or perhaps nonexistent.	Y	N	N	N	N	N	N	N	N	N	N			

32	ACC	3	Exposure	N/A	It is critical that EPA establish clear and consistent guidance that defines when Tier-1 model results will trigger more detailed and refined subsequent assessments. In the problem formulation documents, EPA frequently cites regulatory and non-regulatory occupational exposure limits, but it neither clarifies how it would apply these limits during an exposure assessment, nor specifies a process that will be followed should the Tier-1 model results exceed these limits or margins of exposure. In the event that EPA uses threshold triggers for Tier-2 models within EPA's risk assessment process, the Agency must provide guidance regarding how it selects these values and provide stakeholders an opportunity to comment.	Y	N	N	N	N	N	N	N	N	N	N			
33	ACC	3	Exposure	N/A	Similarly, EPA should specify which exposure models—for all routes and populations—it intends to use during the risk evaluation process. In the problem formulations, EPA mentions several different models, but it does not provide rigorous guidance as to which tools will be used under which circumstances. Similarly, EPA does not identify specifically what it considers to be "higher tier models." Exposure models vary in terms of the purposes for which they are used, their input requirements, and assumptions. By providing a rationale for its model selection, the Agency will afford stakeholders an opportunity to provide appropriate data and contribute relevant information to EPA during its risk evaluations.	Y	N	N	N	N	N	N	N	N	N	N			
34	ACC	3	Exposure	N/A	EPA also should be clear about the use of modeled vs. measured data in evaluating exposure. For example, if measured data are rejected in favor of modeled estimates, the rationale for such a decision needs to be clear.	Y	N	N	N	N	N	N	N	N	N	N			
35	ACC	3	Exposure	N/A	EPA participates in the OECD's Working Party on Exposure Assessment (WPEA). In that capacity, EPA has been a global leader helping harmonize chemical use categories and developing standard exposure/emission scenario documents (ESDs) for occupational exposure assessments for chemical regulations. ACC expects that EPA will use these standard exposure scenarios in its occupational exposure assessments, but that is not clear from the problem formulation documents. EPA should clarify this point in its draft risk evaluations of these 10 chemicals and in any new guidance the Agency develops on exposure assessments under TSCA.	Y	N	N	N	N	N	N	N	N	N	N			
36	ACC	3	Exposure	N/A	In addition, EPA should develop additional standard exposure scenarios for both worker and consumer exposures under TSCA. Standard exposure scenarios would assure greater consistency in EPA exposure assessments; improve exposure model parameters; and help industry understand what specific information EPA needs in exposure assessments for TSCA risk evaluations. In short, standard exposure scenarios would improve efficiencies when conducting TSCA risk evaluations, which are critical given TSCA's statutory deadlines. EPA may want to consider stakeholder workshops to discuss ways in which standard exposure scenarios might be developed in the US. If so, EPA should also ensure that standard scenarios developed under REACH be discussed and considered at such workshops since many of these may be useful in TSCA as well.	Y	N	N	N	N	N	N	N	N	N	N			
37	ACC	3	Exposure	N/A	EPA Should Explain What Additional Ecological Exposure Assessment Tools Are Available. The screening-level approaches described in the problem formulation documents are appropriate for this step (i.e., E-FAST), but EPA should identify acceptable tools/methods for higher-tier refinement when necessary. Screening-level exposure analysis may be suitable in cases where estimates do not exceed the Concentration of Concern (COC). EPA should explain how it would use higher-tier information, if provided.	Y	N	N	N	N	N	N	N	N	N	N			
38	ACC	3	Exposure	N/A	EPA has indicated that environmental exposure data may be available for some of these 10 chemicals in the EPA Discharge Monitoring Report tool, EPA's STOrage and RETreival (STORET) system, USGS National Water Quality Assessment (NAWQA) program, and other sources. Some of these data sources may not be current and therefore may not represent the best available information. EPA should clarify exactly how it would use such data to establish a national, regional, or local environmental exposure estimate.	Y	N	N	N	N	N	N	N	N	N	N			
39	ACC	3	Exposure	N/A	EPA should also clarify how it will quantify and assess (or exclude) naturally-occurring sources of chemicals for assessment during exposure estimation.	Y	N	N	N	N	N	N	N	N	N	N			
40	ACC	3	Exposure	N/A	EPA's Consumer Exposure Model (CEM) is mentioned as the preferred tool for estimating consumer exposures in several of the first 10 chemicals' risk evaluations. This model is publicly available. However, another model mentioned by EPA is the Multi-Chamber Concentration and Exposure Model (MCCEM). This model is available on EPA's exposure tools website, but in a version (Windows 95 operating environment) that will not run on currently available platforms. EPA should ensure that all the models it uses in its assessments are publicly available in a form that is accessible to the general public, complete with explanations on how to use the model and how the exposure endpoints are estimated.	Y	N	N	N	N	N	N	N	N	N	N			
41	ACC	3	Exposure	N/A	The problem formulations for most of the 10 chemicals indicate that the chemical is found in either formulated products used by consumers or in articles with which consumers could come into contact. It is not clear how EPA will assess consumer exposures to these products. The exposure assessments must be able to estimate the consumer exposures from these chemicals based on whether they are found in formulated products or articles.	Y	N	N	N	N	N	N	N	N	N	N			
42	ACC	3	Exposure	N/A	For chemicals that are primarily in articles, the approach and rationale for estimating consumer exposures should be described in detail because exposure assessments from articles are a new area of assessment. Industry and other stakeholders may not be familiar with the rationale and approaches used to estimate exposures from articles. The scientific basis for determining exposures from chemicals in articles must be established for the Agency to meet the statutory standard that requires TSCA risk assessments to quantify the likely (i.e., having a high probability of being true) duration, intensity, frequency, and number of exposures under the conditions of use. EPA should clearly identify the criteria for and scope of the tools chosen to be used in each circumstance.	Y	N	N	N	N	N	N	N	N	N	N			
43	ACC	3	Exposure	N/A	For exposure assessments, EPA may need to make decisions about which products to focus on in the assessments among the various potential products in which the chemical may be found. To conduct the consumer exposure assessment, the assessor may need to focus on representative products in some of these use categories. The product types chosen to be used in the exposure models, the exposure routes, most relevant exposure scenarios, exposure endpoints, and rationale for the choices must be described. The greater the clarity and transparency of these explanations, the greater the likelihood the final assessment will be understood.	Y	N	N	N	N	N	N	N	N	N	N			
44	ACC	3	Exposure	N/A	EPA states in several of the problem formulations that TRI data will be used as a source of information on releases to the environment. TRI data may have a role to play as an element in chemical prioritization, but these data also have limitations. EPA states on the TRI website: [The Toxics Release Inventory (TRI) provides data about environmental releases of toxic chemicals from industrial facilities throughout the United States, measured in pounds. The quantity of releases, however, does not indicate the level of health risk posed by the chemicals. Although TRI data can't tell you whether or to what extent you've been exposed to these chemicals, they can be used as a starting point in evaluating potential risks to human health and the environment.] EPA readily acknowledges in its TRI National Analysis 2016: Releases of Chemicals that "[h]uman health risk resulting from exposure to toxic chemicals are determined by many factors…" These factors include environmental fate, individual exposures, chemical properties, and concentration, none of which are furnished through the TRI. For a chemical to present a risk, there must be a sufficient pathway and exposure, factors that TRI does not address. EPA should acknowledge and explain the limited value of TRI data in risk evaluation.	y	N	N	N	N	N	N	N	N	N	N			
45	ACC	3	Exposure	N/A	Biomonitoring information is identified in several of the problem formulations as a type of data/information source for TSCA risk evaluations, but there is limited discussion of how or where it would be used. EPA should address in guidance the specific biomonitoring information it would rely upon in TSCA risk evaluations and how it would be used. Canada uses "biomonitoring equivalents" in its risk assessments under the Canadian Management Plan (CMP). EPA should examine how those values, as well as Canada's assessments that are based upon them, might be used in the TSCA exposure assessments.	y	N	N	N	N	N	N	N	N	N	N			

46	ACC		3	Human Health	N/A	It is important that a multidisciplinary review process, which integrates hazard information and data from in vitro and in vivo studies across different biological levels of organization for a given exposure scenario, be established for hazard evaluation, data review, and decision making contexts. Typically, this should be a transparent and structured analysis using the Bradford Hill causal considerations and, in particular, biological plausibility and empirical support (dose response, temporal concordance and consistency). The hazard information must be relevant to the specific exposure scenario and the integration of data should be applied initially for each data stream (epidemiology, in vivo, mechanistic) across similar types of study endpoints. The lines of evidence (human epidemiology, in vivo toxicity and mechanistic) must then be integrated using a transparent and objective approach. Through such an integrated assessment, evaluators use the entire body of studies and the full weight of the scientific evidence. This approach avoids the pitfalls of selecting the lowest statistically significant finding of a response in a given study (as a default) without adequately framing the risk hypotheses and integrating data from different sources. EPA states in the general response to comments on the initial 10 scope documents that it anticipates using data from alternative test methods for the risk evaluations. This is consistent with the mandate under TSCA Section 4(h) to "reduce and replace, to the extent practicable, scientifically justified, and consistent with the policies of this title, the use of vertebrate animals in the testing of chemical substances or mixtures…"	Y	N	N	N	N	N	N	N	N	N	N			
47	ACC		3	Human Health	N/A	ACC supports EPA's continued efforts to identify, develop, and integrate new approach methodologies (NAMs) for regulatory decision-making according to the EPA OPPT Strategic Plan to Promote the Development and Implementation of Alternative Test Methods. It is important that sufficient scientific confidence in each NAM be established for its intended application before use as a key piece of evidence in a hazard evaluation and limitations be acknowledged. It is equally important that exposure information, at a fit-for-purpose level of resolution, is available to place these data into a risk context.	Y	N	N	N	N	N	N	N	N	N	N			
48	ACC		3	Human Health	N/A	EPA acknowledges that it must further analyze the MOA for cancer risk in the problem formulations. ACC supports that analysis. The AOP framework is a tool to systematically organize available data and knowledge that describes scientifically plausible and causal relationships across multiple levels of biological organization between a molecular initiating event (MIE) and subsequent key events (KEs), culminating in an adverse outcome (AO) potentially relevant to risk assessment. EPA researchers have been instrumental in developing AOPs and tools to facilitate the further development, review, and use of AOPs in scientific and regulatory endeavors. Tools such as the AOP wiki can be mined for additional data and organizational principles as well as domains of applicability for various identified MOAs associated with chemicals. Thus, whether evidence generally aligns or does not align with any proposed or known MOAs and/or AOPs should be a necessary consideration in integrating evidence to reach conclusions.	Y	N	N	N	N	N	N	N	N	N	N			
49	ACC		3	Human Health	N/A	The Agency's focus on dose-response data and models reflects the fact that toxicology has evolved over the past 35 years from a largely observational field of study to a discipline that applies advanced scientific techniques and knowledge to investigate how chemicals interact with biological systems at the molecular, cellular, organ, and organism levels to understand the biological basis for the induction of toxicity. As a consequence of rapid advances in scientific understanding and the application of this knowledge to regulatory science policy and risk assessments, risk assessors can now evaluate biological events leading to toxicity and consider how, in a dose-response manner, these events relate to potential risks to human health. Despite the significant progress, movement away from default assumptions has been slow to occur, particularly in certain EPA programs. Failure to recognize and act on advances in scientific knowledge and the best available, most relevant scientific data and dose response models wastes significant research and development investments. It is also contrary to the TSCA Section 26 requirement that EPA rely upon best available science in science-based Section 6 decisions.	Y	N	N	N	N	N	N	N	N	N	N			
50	ACC		3	Human Health	N/A	In its 2005 Cancer Guidelines, EPA is clear that when risk assessments are performed using only one set of procedures, it may be difficult for risk managers to determine how much health protection is built into a particular hazard determination or risk characterization. EPA's Cancer Guidelines state:[When there are alternative procedures having significant biological support, the Agency encourages assessments to be performed using these alternative procedures, if feasible, in order to shed light on the uncertainties in the assessment, recognizing that the Agencymay decide to give greater weight to one set of procedures than another in a specific assessment or management decision.] In addition, the Agency says: [If critical analysis of agent-specific information is consistent with one or more biologically based models as well as with the default option, the alternative models and the default option are both carried through the assessment and characterized for the risk manager. In this case, the default model not only fits the data, but also serves as a benchmark for comparison with other analyses. This case also highlights the importance of extensive experimentation to support a conclusion about mode of action, including addressing the issue of whether alternative modes of action are also plausible.] These statements are related to comment 50.	Y	N	N	N	N	N	N	N	N	N	N			
51	ACC		3	Human Health	N/A	EPA's Office of Pesticide Programs (OPP) has adopted the World Health Organization (WHO)/International Programme on Chemical Safety (IPCS) MOA framework for organizing, evaluating, and integrating hazard and dose response information. The same approach should be adopted for TSCA assessments. The MOA framework can be used to illustrate the key events in a known toxicity pathway to address whether a reported statistically-significant response is consistent with what is expected based upon knowledge of the biological responses comprising the pathway. It should be noted that even if early biological responses/perturbations are detected, these observations are not necessarily adverse or precursors to adverse effects in living organisms because of adaptive or homeostatic mechanisms. To reliably predict toxicity, key events need to be causally linked to adversity with a clear understanding of dose response/temporal key event relationships. EPA should adopt and use the standard MOA templates for both cancer and non-cancer endpoints, such as the dose/temporal concordance and species concordance templates. These templates have been incorporated by the European Chemicals Agency (ECHA) in implementing Europe's REACH program.	Y	N	N	N	N	N	N	N	N	N	N			
52	ACC		3	Human Health	N/A	Because the scientific justification for assessing human relevance and selecting dose-response extrapolation methods for quantifying risks at environmentally relevant levels of exposure is highly dependent upon the determination of the likely operative MOA, the Agency should implement a uniform, systematic and explicit approach for evaluating a chemical dataset, using hypothesized MOAs and the evolved Bradford Hill causal considerations, to integrate evidence and derive weight of the evidence (WOE) confidence scores for potentially relevant MOAs. This approach enables a side-by-side comparison of numerical WOE confidence scores for different hypothesized MOAs, including the default linear-no-threshold model, which permits better identification of the likely best MOA to use. The side-by-side quantitative MOA WOE confidence scoring method enhances transparency and improves communication amongst risk managers and the public. Furthermore, the best available science approach provides a transparent, scientifically sound justification for using the most likely operative MOA as the basis for selecting the most appropriate extrapolation method that corresponds to that MOA to then calculate potential risks to humans for environmentally relevant exposures.	Y	N	N	N	N	N	N	N	N	N	N			

53	ACC	3	Human Health	N/A	To illustrate this method, a case example has been developed based on data of rodent liver tumors induced by carbon tetrachloride (Attachment B-attached in the ACC coments on Problem Forumulation 46 August 2018). This case example used data and lines of evidence from previously published review articles, and relied on those authors' evaluations of the quality of the empirical evidence. Two hypothesized MOAs were evaluated: 1) induction of rodent liver tumors via a mutagenic MOA; and 2) induction of rodent liver tumors via a cytotoxicity MOA. The quantitative MOA WOE confidence scoring results of this case example indicate: (1) it is highly unlikely that carbon tetrachloride induces rodent liver tumors via a mutagenic MOA and (2) Cytotoxicity and sustained regenerative cellular proliferation is the like operative MOA for induction of liver timors in rodents by carbon tetrachloride; there are significant mechanistic data to support thos non-linear, non-mutagenic MOA. Based on the comparison of quantitative MOA WOE confidence scores, there is strong scientific support for using a threshold extrapolation approach for evaluating the cancer risks of carbon tetrachloride. (In contrast, scientific justification is lacking to support a linear, no threshold extrapolation method for evaluating its cancer risks.)	N	N	N	N	N	N	N	N	N	N	N			
54	ACC	3	Human Health	N/A	Finally, another challenge in extrapolating animal data to human data involves having an understanding of the relative toxicokinetics. Significant strides have been made using physiologically based pharmacokinetic (PBPK) data and models in risk assessment to improve the accuracy of deriving dosimetry considerations. However, it is important to recognize that some animal studies using conventional maximum tolerated doses (MTDs) are flawed and cannot be used to extrapolate to human doses because they exceed the kinetically-derived maximum dose (KMD). In a number of cases, substances show dose-dependent transitions in their mechanisms of toxicity. This circumstance needs to be evaluated appropriately.	Y	N	N	N	N	N	N	N	N	N	N			
55	ACC	3	Eco Health	N/A	EPA has used a simple approach to calculate the acute and chronic COCs, i.e., dividing the lowest study value by an assessment factor. Conservative, screening-level approaches, such as those utilized in the EPA's New Chemicals Program, can be appropriate to provide context at the problem formulation stage. However, in future scoping documents EPA should clarify the circumstances under which further, higher-tier evaluation would be triggered, if necessary (e.g. species sensitivity distribution, etc.).	Y	N	N	N	N	N	N	N	N	N	N			
56	ACC	3	Eco Health	N/A	EPA should identify more sophisticated higher-tier approaches it may use for determining a hazard threshold, especially for data rich chemicals. Toxicity information, and when available, knowledge of mechanisms, are integrated with exposure-response models for risk-based environmental safety decision making. Within an environmental context, the assessment of safety does not end at the organism, but includes extrapolation to populations, communities, and ecosystems. For ecological risk assessment, the possibility of obtaining site-specific population data is a critical option for higher-tier assessment.	Y	N	N	N	N	N	N	N	N	N	N			
57	ACC	3	Eco Health	N/A	EPA should also consider the unique physico-chemical properties that can impact substances' pharmacokinetics and toxicity profiles, as well as their environmental fate and distribution.	Y	N	N	N	N	N	N	N	N	N	N			
58	ACC	3	General	N/A	Conclusion: ACC commends EPA on its efforts to gather the best available information for the problem formulation documents for the initial 10 chemicals undergoing risk evaluation under amended TSCA. EPA has demonstrated some screening-level assessment techniques that allow EPA to focus on the conditions of use that pose the greatest potential for risk. However, in situations where EPA may need to perform higher tier assessments for the risk evaluation, more guidance and information is needed on the types of data and techniques that EPA will utilize. This will enable industry to better understand how to provide EPA with the information it needs to perform high quality risk evaluations.	Y	N	N	N	N	N	N	N	N	N	N			
59	APHA	1	Exposure	N/A	TSCA is EPA's primary source of authority for evaluating and managing the health and environmental risks presented by approximately 85,000 industrial chemicals. Unfortunately, the problem formulation documents indicate that the agency intends to conduct risk evaluations that are incomplete and likely to underestimate risk. Specifically, the agency plans to ignore numerous exposures to these chemicals. By considering only some exposures and not others, EPA likely will conclude that the total level of exposure to a chemical is lower than it truly is. The agency then may determine incorrectly that this lower level of exposure does not present an unreasonable risk of injury to health or the environment, even when the true level of exposure does present such a risk. The decision to ignore chemical exposures is unlawful and lacks scientific credibility. EPA should include all exposures to these chemicals in its risk evaluations.	Y	N	N	N	N	N	N	N	N	N	N			
60	APHA	1	Exposure	N/A	EPA's problem formulation documents indicate several ways in which the agency intends to ignore exposures to the chemicals. First, TSCA requires EPA to "conduct risk evaluations…to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment…under the conditions of use." TSCA § 6(b)(4)(A) (emphasis added). In general, "the conditions of use" of a chemical include the manufacture, distribution in commerce, processing, use, and disposal of the chemical. EPA has decided to ignore conditions of use and resulting exposures, either by declaring that certain activities are not conditions of use or by acknowledging that the activities are conditions of use but nonetheless declaring that they will not be included in the risk evaluation. These actions by the agency lack both legal and factual support.	Y	N	N	N	N	N	N	N	N	N	N			
61	APHA	1	Exposure	N/A	Second, EPA has decided to exclude entire exposure pathways, such as inhalation of a chemical in ambient air or ingestion of a chemical in drinking water, from the risk evaluations. These exclusions rely on a flawed analysis of TSCA and other environmental statutes. Furthermore, EPA admits the exclusions will disregard important risks of injury to health.	Y	N	N	N	N	N	N	N	N	N	N			
62	APHA	1	Exposure	N/A	The exclusion of certain activities from the risk evaluations is unlawful. As noted above, TSCA requires EPA to evaluate the risks presented by "a chemical substance" under "the conditions of use." The language of the statute clearly directs the agency to evaluate the risk presented by a chemical substance in total and does not provide for picking and choosing among conditions of use when conducting a risk evaluation. Even if EPA did possess the authority to include only some conditions of use and not others, however, the agency still has failed to support its exclusions with information provided in the problem formulation documents.	Y	N	N	N	N	N	N	N	N	N	N			
63	APHA	1	Exposure	N/A	In many cases, it appears that EPA has obtained information via unverified communications with companies that once engaged and still may be engaged in activities that constitute conditions of use. These include manufacturers, processors, distributors, commercial users, and companies involved in disposal of one or more of the chemicals. It does not appear that EPA has taken meaningful steps to verify information provided by companies or their representatives. This is inappropriate due to the obvious conflicts of interest with respect to risk evaluations for chemicals that once were or still are important to their businesses.	Y	N	N	N	N	N	N	N	N	N	N			
64	APHA	1	Exposure	N/A	For example, EPA has concluded that "domestic manufacture of HBCD has ceased" based primarily on assurances provided by two recent manufacturers of the flame retardant. The agency does not indicate how it verified these assurances or how it will ensure that the purported cessation will continue in the future.	N	N	N	N	N	Y	N	N	N	N	N			
65	APHA	1	Exposure	N/A	EPA relies on information from entities even after concluding that the information is not credible.	Y	N	N	N	N	N	N	N	N	N	N			
66	APHA	1	Exposure	N/A	For example, the agency relies on information from "several racing authorities" to conclude that dioxane is no longer used as a fuel additive in car racing. Even though the racing authorities "could not provide credible information on…whether [dioxane] is currently used at all," the agency nonetheless determined that "fuels and fuel additives" are not a condition of use for the purposes of the 1,4-dioxane risk evaluation and will be excluded.	N	N	Y	N	N	N	N	N	N	N	N			
67	APHA	1	Exposure	N/A	Even if the information provided by a company is accurate, the company remains free to resume any activity at any point in the future absent a regulation stating otherwise. Such an activity therefore remains a "reasonably foreseeable" condition of use under the statute. Furthermore, accurate information that may be provided by one company or subset of companies cannot be assumed to represent the activities of all current or future firms within an industry. Yet EPA makes this assumption.	Y	N	N	N	N	N	N	N	N	N	N			

68	APHA		1	Exposure	N/A	The agency has excluded domestic manufacture of expanded polystyrene (EPS) resin and extruded polystyrene (XPS) masterbatch from the HBCD evaluation based on reports by “all major North American manufacturers…of EPS resin” and comments by “major producers” of XPS masterbatch (emphasis added), respectively. These reports cover only manufacturers or producers that the agency considers “major.” They cannot represent the activities of any other manufacturers of EPS resin or XPS masterbatch, including any future manufacturers.	N	N	N	N	N	Y	N	N	N	N	N			
69	APHA		1	Exposure	N/A	At a minimum, if EPA is told that manufacture, import, and processing of a chemical has ceased, the agency should demand legally binding certification of such cessation from every previous manufacturer, importer, and processor of the chemical. Furthermore, the agency should promulgate a significant new use rule under TSCA § 5(a) so that, if and when manufacture, import, or processing of the chemical does occur in the future, the activity must be reported to EPA.	Y	N	N	N	N	N	N	N	N	N	N			
70	APHA		1	Exposure	N/A	In addition to ignoring conditions of use, EPA intends to disregard entire pathways of exposure to chemicals. By disregarding these pathways, EPA will narrow the scopes of the risk evaluations further. In addition, for every chemical except pigment violet 29, EPA argues it can ignore exposures resulting from disposal. By excluding pathways, the agency will ignore potential exposure to more than 68 million pounds of industrial chemicals released each year. EPA’s rationale for excluding pathways disregards TSCA and, by the agency’s own admission, ignores unreasonable risks of injury to health.	Y	N	N	N	N	N	N	N	N	N	N			
71	APHA		1	Exposure	N/A	For example, even if domestic manufacture of 1,4-dioxane is included in the scope of the risk evaluation, inhalation of 1,4-dioxane in ambient air or ingestion of 1,4-dioxane in drinking water as a result of releases by domestic manufacturers will be excluded.	N	N	Y	N	N	N	N	N	N	N	N			
72	APHA		1	Exposure, RegNex	N/A	According to the agency, exposure pathways will be excluded when they fall under “other environmental statutes, administered by EPA, which adequately assess and effectively manage exposures and for which long-standing regulatory and analytical processes already exist[.]” There are key differences between the requirements imposed by “other environmental statutes” and the requirements imposed by TSCA.	Y	N	N	N	N	N	N	N	N	N	N			
73	APHA		1	Exposure, RegNex	N/A	For example, EPA intends to exclude inhalation of methylene chloride in ambient air. The agency claims that, because methylene chloride is listed as a hazardous air pollutant under the Clean Air Act, this pathway is “adequately assess[ed] and effectively manage[d]” under another statute and need not be considered under TSCA. This is incorrect. EPA manages hazardous air pollutants by requiring source categories to reduce emissions based on what is achievable using certain technologies. The agency does not require source categories to eliminate all emissions, and the remaining emissions can present significant risks. In the case of methylene chloride in ambient air, there is no reason to believe that exposure and risk are effectively managed. As the agency acknowledges, “levels of methylene chloride in the ambient air are widespread and shown to be increasing.”	N	N	N	N	N	N	N	Y	N	N	N			
74	APHA		1	Exposure, RegNex	N/A	EPA is required to evaluate the risk presented by chemicals under TSCA. This includes any risks to vulnerable populations. The agency cannot escape this requirement by ducking behind unrelated statutes that impose separate requirements to protect public health.	Y	N	N	N	N	N	N	N	N	N	N			
75	APHA		1	Exposure	N/A	EPA admits that excluding exposure pathways will neglect unreasonable risks of injury to health presented by the chemicals.	Y	N	N	N	N	N	N	N	N	N	N			
76	APHA		1	Exposure	N/A	For example, the agency said it intends to exclude exposure to 1,4-dioxane in drinking water because drinking water contaminants may be regulated under the Safe Drinking Water Act. (Notably, the agency does not regulate 1,4-dioxane under the Safe Drinking Water Act, nor has it proposed to do so.) EPA acknowledges that “[t]he general population may ingest 1,4-dioxane via contaminated drinking water.” EPA reports that 341 water systems have measured 1,4-dioxane at concentrations associated with an excess cancer risk greater than or equal to one in one million. This level of risk “has often been considered a “benchmark” above which EPA has concerns for exposure to the general population” — that is,the agency has considered this level of risk to be unreasonable. Because EPA is excluding drinking water exposure to 1,4-dioxane from the risk evaluation, however, this unreasonable risk will be ignored.	N	N	Y	N	N	N	N	N	N	N	N			
77	APHA		1	PESS	N/A	TSCA requires EPA to determine whether a chemical presents an unreasonable risk of injury to the general population and/or to “potentially exposed or susceptible subpopulations.” §6(b)(4)(A). A potentially exposed or susceptible subpopulation is any “group of individualswithin the general population…who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population…such as infants, children, pregnant women, workers, or the elderly.” § 3(12). It is well understood, for example, that pregnant women, children, and infants are uniquely susceptible to chemical exposures. TSCA imposes a duty on EPA to ensure that vulnerable subpopulations are protected from chemical risks, and it is imperative that the agency conduct risk evaluations, make risk determinations, and promulgate risk management regulations in accordance with this duty. In particular, TSCA provides new tools to protect workers from occupational exposures to a wide variety of chemicals encountered while on the job. Workers face significant risk of harm from chemical exposures but they are not adequately protected by regulations of the Occupational Safety and Health Administration. OSHA has adopted comprehensive health standards on just a few dozen chemicals since the agency was established in 1971, and most of these standards were issued before 1990.25 Furthermore, tens of millions of workers are not covered by the Occupational Safety and Health Act. EPA’s duty to protect workers and other vulnerable subpopulations under TSCA fills in gaps in the law that have allowed workers to go unprotected from chemical hazards.	Y	N	N	N	N	N	N	N	N	N	N			
78	NTTC		1	PESS	N/A	Affirmed by the Supreme Court, it is the law of the land that federal agencies must fulfill a legally-binding trust responsibility to protect tribal trust resources and must uphold U.S.-Tribal treaty agreements. As the federal regulatory agency charged with environmental protection, this duty is relevant to EPA’s implementation of TSCA because tribes have high exposure to the natural environment, dietary reliance on local wild foods, and unique customary and traditional practices.Thus, under TSCA, tribes meet the definition of an exposed subpopulation, and EPA must adequately and transparently evaluate these exposures. The National Tribal Toxics Council (NTTC) is the Office of Pollution Prevention and Toxics (OPPT) Tribal Partnership Group to represent the collective interests of the 576 federally-recognized sovereign tribal nations across the United States, located within all 10 EPA regions. Together, 6.1 million tribal members are represented.	Y	N	N	N	N	N	N	N	N	N	N			
79	NTTC		1	PESS	N/A	A risk assessment based on the HBCD Problem Formulation will not be protective of tribal, rural, or urban subsistence populations as it fails to identify exposed subpopulations. Consequently, unless the Problem Formulation is changed to explicitly address these populations, the EPA Administrator will fail to carry out requirements as mandated by Congress in TSCA, as amended, June 22, 2016.	N	N	N	N	N	Y	N	N	N	N	N			
80	NTTC		1	PESS	N/A	NTTC takes issue with the methodology used in identifying relevant literature for the scoping document. Arguably, the greatest change in TSCA is the mandate of health-based assessment and the inclusion of sensitive and exposed subpopulations in identifying the health risk of chemicals to the American people. Yet, while tribal based risk scenarios are readily available, they are not addressed in the Problem Formulation, and there is no evidence that an attempt was made to include them. Tribes are simply not mentioned, whether it be in the literature search or bibliography, the narrative, or conceptual model. The same holds for ethnic-urban subsistence and rural subpopulations.	N	N	N	N	N	Y	N	N	N	N	N			

81	NTTC	1	PESS, Exposure	N/A	The EPA Office of Solid Waste is aware that permitted unlined municipal, and construction and demolition landfills are prevalent in Indian Country. The practice of open burning in burn barrels is widespread, and in Alaska Native villages the entire community wastestream is regularly burned without emissions control under a RCRA permit. Wild foods that the tribes depend on for their diet can be contaminated with HBCD via leachate and smoke, and whole communities can be exposed via inhalation and direct contact with wastes. Extruded and Expanded Polystyrene (XPS and EPS) insulation products are ubiquitous in Alaska and are used in ceilings, floors, interior walls, outside finished exterior walls, foundations and foundation wings, road beds, and more. The construction and demolition waste products, both residential and commercial, are brought to the unlined municipal landfills and dumpsites, or to unlined project-specific dumps. Nearly three-quarters of villages are within one mile of these disposal sites and their diets are dependent on locally hunted, fished, and gathered foods. Over eighty percent of these villages practice open burning, and because the sites are proximate, smoke from these disposal practices is commonly smelled by village residents. Even under the EPA's narrow Conditions of Use requirement, the resultant exposure scenarios for Alaska tribes, as well as Alaska rural residents that comprise more than half the population of the state, are left out. Many tribes are small communities with members being exposed in multiple ways. For example, the same worker who helped in the sawing of EPS board may be the landfill worker that carries the board to the dump and burns it, then goes home to their family where, now part of the community's "bystander" population, they have additional exposures by breathing the smoke, and consuming food and water that is contaminated from leachate.	N	N	N	N	N	Y	N	N	N	N	N			
82	NTTC	1	Exposure, General	N/A	Beyond the clear primary issue to Tribes of the absence of tribally-specific risk scenarios in the problem formulation, NTTC further takes issue with the following critical points that relate to the problem formulations in general and prevent the performance of a valid health assessment for tribes and other Americans as intended by Congress: -Omission of legacy use, particularly the use and disposal of products that are still in active service life. For example, it is unclear why the widespread use and disposal of millions of computers and other electronics known to contain HBCD is not considered in the problem formulation. -Omission of conditions of use considered to be under the purview of other Federal Environmental Statutes that focus primarily on priority pollutants. TSCA was amended specifically because Congress found that these same existing environmental laws did not adequately protect the American people. -Omission of products knowingly or reasonably foreseen to incorporate HBCD and the complete omission of recycled products due to a perceived 'lack of intention' in fitting the Administrator's narrowly defined Conditions of Use. For example, the use and disposal of picture frames, food trays, coolers, and other products knowingly made with recycled EPS of high HBCD content is not considered. The decisions taken by EPA on these points were spurious and each are clearly inconsistent with the science and purpose of risk assessment and TSCA itself.	Y	N	N	N	N	N	N	N	N	N	N			
83	NTTC	1	PESS	N/A	The following relevant language is excerpted from the Toxic Substances Control Act of 2016, as amended, pertaining to potentially exposed or susceptible subpopulation and to high-priority substances, and from the U.S. EPA Office of Chemical Safety and Pollution Prevention's May 2018 Problem Formulation for Cyclic Aliphatic Bromides Cluster (HBCD) respectively, with emphasis added relevant to the below comments. The term "potentially exposed or susceptible subpopulation" means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly. The Administrator shall designate as a high-priority substance a chemical substance that the Administrator concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator. For HBCD, EPA considers workers, occupational non-users, consumers, and bystanders and certain other groups of individuals who may experience greater exposures than the general population due to proximity to conditions of use to be potentially exposed or susceptible subpopulations. EPA will evaluate whether groups of individuals within the general population may be exposed via pathways that are distinct from the general population due to unique characteristics (e.g., life stage, behaviors, activities, duration) that increase exposure, and whether groups of individuals have heightened susceptibility, and should therefore be considered potentially exposed or susceptible subpopulations for purposes of the risk evaluation.	N	N	N	N	N	Y	N	N	N	N	N			
84	NTTC	1	PESS, General, Exposure	N/A	As currently practiced, the proposed conceptual models of the first ten problem formulations issued May 2018 do not meet the standard of relevance and representation for Tribal peoples, and therefore the model implementation process is essentially moot, and the applicability of the model to the 6.1 million people that Tribes represent is irrelevant.	Y	N	N	N	N	N	N	N	N	N	N			
85	NTTC	1	General, Exposure	N/A	We use the commonly accepted definitions of key terminology in risk assessment science. The following excerpts are drawn from the International Programme on Chemical Safety (IPCS) glossary (2004)3 and the Principles of Characterizing and Applying Human Exposure Models (2005)4 as published by the World Health Organization. Exposure assessment is "The process of estimating or measuring the magnitude, frequency, and duration of exposure to an agent, along with the number and characteristics of the population exposed. Ideally, it describes the sources, pathways, routes, and the uncertainties in the assessment" (IPCS, 2004). Exposure assessment is used in epidemiological studies to relate exposure concentrations to adverse health outcomes. Exposure assessment is also an integral component of risk assessment, the process that provides scientific information for risk management. Exposure assessment is based on exposure scenarios, which are defined as "A combination of facts, assumptions, and inferences that define a discrete situation where potential exposures may occur. These may include the source, the exposed population, the time frame of exposure, microenvironment(s), and activities. Scenarios are often created to aid exposure assessors in estimating exposure" (IPCS, 2004). An exposure model is a computational framework designed to reflect real-world human exposure scenarios and processes. A conceptual model is often illustrated by a block diagram, and it defines the physical, chemical and behavioural information and exposure algorithms by which the model mimics a realistic exposure scenario. … The implementation of an exposure model should reflect the underlying conceptual model. Whenever the exposures of different subpopulations are expected to be different from each other, the exposure assessment probably needs to treat these subpopulations separately.	Y	N	N	N	N	N	N	N	N	N	N			

86	NTTC	1	General, Exposure	N/A	Model evaluation can be seen as a three-step process: -1.The conceptual model must be validated. ...The (causal) relationships between the model input events and the output events must be real, and the nature, or shape, of these relationships must be known — at least approximately. -2.The model implementation must follow the conceptual model. The definitions of input and output variables must effectively describe the events of the conceptual model, and the algorithms and equations must sufficiently follow the true (causal) relationships of these events. -3. Assessing the applicability of the model to a set of specific problems is possibly the most difficult step. This includes evaluating how well the input values really describe the target system. Usually the input values have been measured and contain random or systematic measurement errors. The measured input data range is a combination of data uncertainty and true inherent variability, and in some new applications it is essential to be able to differentiate between the two (e.g. when one or the other dominates the distribution). Sometimes other models, questionnaire data or expert opinions are used in place of measurements to assign values to input variables Each of these inputs may or may not accurately describe the characteristics of the target system. Thus, even when the model is conceptually valid and carefully implemented, the model outputs may not agree with the system outputs.	Y	N	N	N	N	N	N	N	N	N	N			
87	NTTC	1	General, Exposure, PESS	N/A	In several of the following sections, the NTTC provides wide-ranging explanation of the vast extent of activities within tribal lifeways, aspects of "the system" (as referenced above) that needs to be modeled in the risk assessment process. In section 7 NTTC provides a graphic image of tribal lifeways, to provide a visual sense of the realm of all natural resources within tribal lifeways, and multitude of exposure scenarios and exposure pathways by which tribal populations are put at greater risk because their tribal lifeways have not been contained with TSCA risk assessment and risk evaluation processes. Also, in section 7, NTTC proposes the draft Possible Tribal Exposures Conceptual Model which received preliminary review and informal comment in an NTTC meeting with EPA OPPT earlier this year. Though in draft form, NTTC emphasizes that by using this conceptual model when evaluating unreasonable risk of injury to health (or their environment) to a potentially exposed and susceptible subpopulations, EPA will thereby protect both tribal populations and other subpopulations.	Y	N	N	N	N	N	N	N	N	N	N			
88	NTTC	1	General, Exposure, PESS	N/A	In terms of subpopulations, consider how Barzyk (2010) discussed community-based risk assessment: "One of the primary differences between communities is in their patterns of exposure. ... Tools that isolate exposure routes and pathways for a given community and then incorporate toxicity information will lead to a better characterization of risk". This is key when considering potentially exposed and susceptible subpopulations, such as tribal groups whose patterns of exposure can be considered to be the "community" of an eco-region, e.g., the Pacific Northwest could encompass tribes and their lifeways from northern California, northerly along the Pacific coast into British Columbia, Canada and as far as the Prince William Sound in southcentral Alaska, U.S. -1. As currently practiced, the proposed conceptual models of the first ten problem formulations issued May 2018 do not meet the standard of relevance and representation for Tribal peoples, and therefore the model implementation process is essentially moot, and the applicability of the model to the 6.1 million people that Tribes represent is irrelevant. -2. Risk assessment of Tribal peoples for TSCA contaminants found in environmental media is relevant because Tribes are in contact with soil, sediment, and water as much or more than other population groups. -3. But the proposed problem formulations, and the risk assessments are not representative because they do not reflect nor model Tribal lifestyles. An entire population of people (6.1million strong) are not represented in any USEPA risk assessment work to date.	Y	N	N	N	N	N	N	N	N	N	N			
89	NTTC	1	General, Exposure, PESS	N/A	For millennia, tribal cultures were completely synonymous with and inseparable from the land and its resources. Tribes (used throughout this document) includes tribal people, resources, and other interests; interests (as sovereigns, seeking to govern/regulate tribal resources and as proprietors, i.e., holders of rights to land, water, fish, etc.) and the interests of individual Native people (whether they are tribal citizens or not; whether they live on a reservation or not); it is important to encompass tribal members who do not reside on tribal land, usual and accustomed areas, as well as treaty-protected resources; tribal lands as used in this report includes reservations, ceded lands, Usual and Accustomed areas (U&A) as well as communities inclusive of the Alaska Native Villages and Islanders and those without land bases. Continuing today, many tribes, tribal people and their clans are identified in their Native languages and in English translations as the name of singular or multiple seasonal locations or specific animals or insects, e.g. Water's Edge Clan (Navajo), People of the Herring Rock (Tlingit), Where the Water Cuts Through (Po-wo-ge-oweenge), Red Willow Place (Tua-Tah), People of the standing of projecting rock or stone (Seneca), The Place where the locusts were taken out (Cayuga), The River with the two logs across it (Chickaloon).	Y	N	N	N	N	N	N	N	N	N	N			
90	NTTC	1	Exposure, PESS	N/A	The Tribal Lifeway is the prime lifeway for those tribal members. Like a prime number cannot be formed by multiplying two smaller natural numbers, the prime Tribal Lifeway cannot be replaced by adapting other lifeways.	Y	N	N	N	N	N	N	N	N	N	N			
91	NTTC	1	Exposure, PESS	N/A	There are no viable or acceptable alternatives to subsistence resources, cultural-spiritual resources, and other resources of tribal lifeways. -Tribal people cannot buy meat, seafood or plant-based foods that are equivalent in calories and nutrients to their traditional and subsistence foods. Replacing resources based solely on calories or nutrition disregards the cultural and ceremonial aspects of the traditional resource. -- I.e., children and young adults learn to hunt, fish, gather, and then process the resources with an adult and/or elder. They learn the significance of the resource in relation to their ancestry and culture. They learn the inter-dependence of generations, or clans, or villages, or species. They learn the values and priorities of their culture. They learn traditional stories, the purpose of which includes cultural preservation, historical knowledge, and instilling moral values.	Y	N	N	N	N	N	N	N	N	N	N			
92	NTTC	1	Exposure, PESS	N/A	"Tribal lifeways" are inclusive of, but not limited to, economic, cultural, ceremonial, societal, political, recreational, and subsistence practices. Examples of tribal lifeways that may influence tribes' exposure to chemicals in consumer products and the environment include but are not limited to: -Hunting, fishing, gathering, including accessing locations, processing collected items in the field and at home, -Constructing blinds in the field, drying racks, smoke houses -Husbandry (farming/growing) -Gathering, consumption, and everyday use of plants and plant materials (food, teas, medicines, salves, different types of combustibles for smoke generation, collection of firewood or tipi poles, etc.) -Water collection (untreated) -Collecting and processing materials for, and making baskets and other weaving, arts, tools, clothes (using feathers, skin, bones, hides, oils, antlers, etc.; wood, ivory and stone carvings) -Building/carving canoes, sweat lodges, fish weirs and traps, other structures -Bathing/sweat lodge use -Traditional medicine -Ceremonial or powwow activities (dancing, traditional games) -Smoke houses and ceremonies with smoke (fire, locally-harvested wood, sage, etc.) -Making and use of traditional pottery (made from local clays, dyes, etc.)	Y	N	N	N	N	N	N	N	N	N	N			

93	NTTC		1	General, PESS	N/A	Current Federal Indian Policy recognizes Tribal Sovereignty, Federal Trust Responsibility, and Government to Government Relationship, yet tribes today suffer health disparities, experience exposure pathways through tribal lifeways. Treaties are legally binding contracts between sovereign nations that establish those nations' political and property relations. Article VI of the U.S. Constitution holds that treaties "are the supreme law of the land." In return for taking vast Indian holdings and resources (i.e. land), the U.S. promised: Reservation Lands, Continued Sovereignty, Protection, Health Care, Education, Religious Freedom, Some Monies. Through the treaties they negotiated, tribes retained rights of self-government and jurisdiction. [exceprt from the 1855 Treaty with Yakama] Tribal sovereignty means that tribes are independent nations with the right to govern themselves by: Forming their own government, adjudicate legal cases within its boundaries, levy taxes within their borders, establish its membership, and retain government-to-government relationship with the U.S.	Y	N	N	N	N	N	N	N	N	N	N			
94	NTTC		1	General, PESS	N/A	The Federal Government has a trust responsibility to protect tribal lands, assets, resources, and treaty rights, and uphold the promises made when treaties were made. With these recognized responsibilities and rights, Tribes have a unique legal status with the U.S. government. They are neither foreign nations, nor states. Tribes are distinct political communities defined in law as "domestic dependent nations." In the 1831 Cherokee Nation v. Georgia decision, the Supreme Court described the obligation of the U.S. to tribes as that of a guardian to his wards. Subsequent decisions have made it clear that the agencies of the federal government are to be held to the most stringent "fiduciary" (trust) standards. "Trust lands" describe lands held in trust by the U.S. for the benefit of a tribe or individual tribal member which cannot be alienated or confiscated through eminent domain. Additional case law since that 1831 Supreme Court decision confirms federal trust responsibility and protection tribal culture, identity, and ways of life. "Moral obligation of the highest responsibility and trust"-Seminole Tribs v. U.S. (1942). The United States is the trustee of Indian reserved rights, including fishing rights. -See, e.g., Joint Board of Control v. United States, 862 F.2d 195 (1988), 198 (9th Cir. 1988); Muckleshoot Indian Tribe v. Hall, 698 F. Supp. 1504, 1510-1511 (W.D. Wash. 1988). The obligation of the United States as trustee of Indian resources and rights extends to all agencies and departments of the Executive Branch. -See Pyramid Lake Paiute Tribe v. Department of the Navy, 898 F.2d 1410, 1420 (9th Cir. 1990), Covelo Indian Community v. FERC, 895 F.2d 581, 586 (9th Cir. 1990). The right to resort to the fishing places in controversy was a part of larger rights possessed by the Indians, upon the existence of which there was not a shadow of impediment, and which were not much less necessary to the existence of the Indians than the atmosphere they breathed.")U.S. v. Winans, 198 US 371 (1905). "…the Indians reiterated…that they wished to reserve the privilege of using the land for gathering, hunting, and fishing activities. They said that they could not live, deprived of these means of sustenance.Lac Court Oreilles Band of Chippewa Indians v. Leter P. Voigt, Seventh Circuit Court (1983).	Y	N	N	N	N	N	N	N	N	N	N			
95	NTTC		1	General, PESS	N/A	Tribal nations, their governments, and their enrolled tribal members and tribal descendants are present in the United States and continue their ancestral tribal lifeways. There are 573 federally recognized tribes: 229 in Alaska, 110 in California and 234 in 33 other states. There are 61 state recognized tribes in 12 states. As of 2017, the U.S. Census Bureau's annual estimate of the Native American and Alaska Native population was 6.1 million which is 1.7% of the total U.S. population. Further, the Bureau projects that by 2050 the Native American and Alaska Native population will be 8.6 million, 2% of the total U.S. populations. The tribal nations with the largest populations include: Cherokee, Navajo, Choctaw, Chippewa, Sioux, Apache, Blackfeet, and Pueblo. The tribal lands—both trust lands and non-trust and non-reservation lands—accumulate to a collective geographical area today of 56 million acres which is equivalent to the size of Idaho state. Unfortunately, tribal people are afflicted by some of the least desirable statistics in the U.S.: the highest rates of suicide of any racial or ethnic group including white; highest rates of violence against women at more than double the rates of women of other races; overrepresentation in U.S. prisons and jails; historical and generational trauma from loss of people, lands and culture; posttraumatic stress disorder; more likely to have poorer overall physical and mental health and unmet medical and psychological needs; overrepresentation in the U.S. foster care system; and predisposition to heart disease, diabetes, and substance addiction. Many of these physical and mental health disparities are related to the historic and generational traumas, related to poverty induced by loss of people, lands, and language, related to the unmet obligations of the U.S. Government. These health disparities are exacerbated by environmental contaminants and pollutants in and around tribal resources. There is a legacy of toxic pollution on tribal lands and resources: "More than a century of hard rock mining has left a legacy of >160,000 abandoned mines in the Western USA that are home to the majority of Native American lands. …Similar articles could be written focusing on impacts to tribal lands from coal strip mining, from the legacy of military bases, and from oil and gas development." Ineffective policies and the lack of infrastructure lead to environmental contamination through permitted exemptions to waste disposal allowing unlined landfills that accept household hazardous waste and unfiltered emissions from on-the-ground or other open burning. These exemptions also allow waste managers non-collection and non-treatment of landfill leachate. Additionally, tribal lands are commonly used for illegal waste dumping due to the significant void of law enforcement presence.	Y	N	N	N	N	N	N	N	N	N	N			
96	NTTC		1	General, PESS, Exposure	N/A	Despite attempts to disconnect tribes from traditional resources and tribal lifeways, tribal populations maintain a close relationship to the environment. The chemical exposures experienced by tribal people are not extremes of a general population range but consist of many discrete activities with legal protections. NTTC recognizes that prior to the Lautenberg Act, the burden of proof of toxicity was on the U.S.consumer. This is not adequate for the tribal community, especially considering the high-level consumption by tribal members of wild and natural resources as well as the U.S. government's trust responsibility and inability to provide safe water and sewer, and solid waste disposal on many Indian reservations and in many Alaska Native villages.	Y	N	N	N	N	N	N	N	N	N	N			
97	NTTC		1	PESS, Exposure	N/A	"Nonstandard exposure pathways occur under four circumstances: (1) qualitatively nonstandard exposures (e.g., dietary, medicinal, or cosmetic use of unusual plants), (2) quantitatively nonstandard exposure (i.e., high consumption rates, children eating dirt, a very large meal [e.g., feast of fish, whale, deer], high exposure relative to other foods, body size, or age), (3) both nonstandard and excessive exposure (i.e., applying a chemical or cosmetic to skin, potential exposure to chemicals through cultural activities such as sweat baths), and (4) inadvertent exposure as byproducts of other consumptive, social, or cultural practices (i.e., mercury exposure from cultural practices)."	Y	N	N	N	N	N	N	N	N	N	N			
98	NTTC		1	PESS, Exposure	N/A	Due to Tribal lifeways, as a whole, Tribal people ingest, inhale, contact, and dermally absorb chemicals from the natural environment more frequently, for longer periods of time, and in different ways, than the general population. Because Tribal lifeways are unique, these exposures are both qualitatively nonstandard (how people are exposed, such as basket grass softening via mouth) and quantitatively nonstandard (e.g. the amount of fish consumed). Tribal people spend longer periods of time and engage more often in the environmentl conducting unique outdoor traditional activites. Examples: Traditional water use (untreated water collection and consumption); hunting, fishing, gathering; ceremonies; social activities. Tribal people engage more often and spend more time interacting with environmental media, resources, and derived objects. Examples: Ceremonial objets (e.g., ceremonial feathers); artifacts (from generations past used for display, speical ceremonies, repatriation); art, tools from media (clay pots, reed baskets, baleen carving, etc.); food preparation and storage; steam baths with untreated water and full body immersion in untreated water.	Y	N	N	N	N	N	N	N	N	N	N			

99	NTTC	1	PESS, Exposure	N/A	Tribal people are substantially more likely to consume locally and regionally-obtained biota, whether plants, animals, or fish, and in greater quantities and greater diversity. Examples: plants; animals, large land mammals; fish, shell fish; large marine mammals. Regionally, certain traditional style of housing and practices, may present substantially greater exposures. E.g., adobe houses present durable dust and soil ingestion exposures off the charts. E.g., fish drying in Alaska with open burning of the community dump site several times per week, less than one quarter mile away, or fish, marine mammal, land animal dried and stored without a protective barrier in the arctic entryway where opened vehicle care products, paints, and other hazardous products are stored. Village housing, school, and landfill are all proximate within a compact area. Children playing in open space available like near vehicles, landfill sites, waste collection sites. There are a umber of facets related to traditional/cultural practices that are not reflected in the activity profiles currently used. Examples: Tribal people's lifestyles are largely seasonal and that dependence on season permeates their daily lives. Seasons are defined not by dates but by changes in the environment and the cycles of plants and animals tribes depend on. Work is often at home, and home environments reflect tribal lifestyles as do the handicraft or ceremonial objects they or extended family members may make. Dust is created by making handicraft and ceremonial objects, mixing with dust accumulated from dirt and gravel roads, furniture, and household products. Thus, dust inhalation and ingestion are major exposure pathways. Age groups are affected. Young children hunt and gather, elders may be more active in the environment longer than their peers in the general populations and serve as babysitters more often, usually living in the same home. Through established practices of sharing resources, the entirety of the Tribe can be exposed.	Y	N	N	N	N	N	N	N	N	N	N			
100	NTTC	1	General, PESS, Exposure	N/A	The below Graphic illustrates the unique exposures that Tribes face and that should be considered in any risk assessment procedure. The conceptual model that follows is intended for use in formulating the scope of any EPA chemical risk assessment. *See Conceptual Model Figures.* [Part 7, pages 10-11, presents a Conceptual Model of Tribal Exposures including a graphic reproduction and a flowchart]	Y	N	N	N	N	N	N	N	N	N	N			
101	NTTC	1	PESS, Exposure	N/A	Exposure measures or models aspects of frequency, duration, and intensity. As such there are multiple additional exposure routes that EPA must evaluate. NTTC maintains that resource use is another important factor to the risk paradigm which EPA is overlooking. EPA must consider whether tribes use different resources that results in different exposure routes(s) than the general consumer. For example, plants uptake the pollutants or pollutants adhere to plants, tribal members harvest those plant resources for customary and traditional foods and medicines, and for traditional arts such as basketry, thus demonstrating multiple exposure pathways including ingestion, dermal absorption on the hands, and in some cases, dermal absorption in the mouth from splitting roots or softening materials. The three steps in the process are (1) Identifying exposure pathways based on the media and resource that is contaminated, (2) Identifying the route of exposure (what is the portal of entry into the person), and (3) Developing exposure factors (the numerical representations of the exposures).	Y	N	N	N	N	N	N	N	N	N	N			
102	NTTC	1	PESS, Exposure	N/A	Thus, exposure assessors must consider data about three prime exposure factors, frequency, duration, and contact rate: -what products Tribes use in their daily lives (e.g., PBDE and/or HBCD-laden older upholstered furniture or bisphenol A (BPA)-infused plastics); -aspects of where they reside that may be non-standard, including but not limited to: proximity to an industrial emissions source, transportation corridor and utilidors, proximity to waste disposal burning and leachate, downriver of or adjacent to a contaminated site, closely-housed communities with only dirt roads, arctic entries where hazardous chemicals are co-located with food and water, aged home furnishings containing long-since banned chemicals breaking down into dust and thus increased inhalation and ingestion, rural locations more likely near open burning and more likely to have vehicles and other solid waste illegally disposed of in their environment, incomplete plumbing and incomplete kitchens—which are found in 7 percent of tribal homes compared with less than 2 percent of all U.S. households. For example, 36 percent of Alaska tribal area households have incomplete plumbing, incomplete kitchens, or overcrowding. -how much time tribes spend engaged in various activities at differing levels of cardiovascular vigor (e.g., sleeping, sitting, exercising, hunting) in various locations (e.g., indoors at work, outdoors in a garden, gathering wild foods in a national forest or a utility right-of-way sprayed with herbicides); -the quantities of various food, drink, and traditional medicinal items ingested; and -how all of these vary over a lifetime.	Y	N	N	N	N	N	N	N	N	N	N			
103	NTTC	1	PESS, Exposure	N/A	Examples of subsistence, traditional, and ceremonial-spiritual activities that should be considered affected by chemicals in consumer products and the environment include but are not limited to: -Collection and use of edible and medicinal resources and cultural materials on public lands such as utility rights of way, streambeds, and marshes. This may include wading and constant soaking of feet and hands in water during collection activities. -Preparation of traditional materials, including cleaning in surface water and other activities such as chewing reeds, sinew, and fish skins for additional uses. -High consumption of plants gathered and fish and animals (including shellfish and other invertebrates) collected locally, including non-standard consumption such as fish skin, fats and oils, or other parts of animals, most of which are not readily available in the supermarket. -Meditation, bathing, steam baths, cooking, cleaning, soaking traditional materials (also placed in mouth while conducting multiple activities), and drinking local surface and rain water and snow and ice melt. -Smoking fish/meats and hides, burning out canoes, cultural burning to stimulate material production, and heating rocks for cooking, shaping wood and sweat lodges. -Occupational and environmental exposures are also often overlooked. For example, a study of malignant mesothelioma found that Native American silversmiths routinely used asbestos mats to insulate worktables while making silver jewelry, which exposed them to a hazard, asbestos, that was seemingly unrelated to the occupational activity (silversmith).	Y	N	N	N	N	N	N	N	N	N	N			
104	NTTC	1	PESS, Exposure	N/A	Regarding the population scenario, the tribal population scenario is the most appropriate to use for risk assessments by EPA because TSCA requires EPA to protect the population of highest risk. Additionally, it is a federal trust responsibility to tribes under the U.S. government's moral and legal obligations to American Indians and Alaska Natives. EPA must use the fish consumption rates of subsistence fishers so that EPA accounts for aggregate exposure of those who rely heavily on locally sourced fish. Consider that EPA identified in the 2015 problem formulation for the HBCD cluster, the fish consumption rate of 142.5 grams based on subsistence fishers consumption rates (U.S. EPA, 2015a). Furthermore, there are EPA-accepted rates several times higher in Region 10.	Y	N	N	N	N	N	N	N	N	N	N			
105	NTTC	1	General, PESS, Exposure	N/A	NTTC supports EPA's comments on the September 30, 2015 technical call (U.S. EPA, 2015b) that EPA will evaluate additive exposures, such as oral exposures including fish consumption, drinking water consumption, potential for dust consumption and mouthing in the flame retardant risk assessments. However, in such an evaluation of oral exposures, EPA must include the high-end exposure approach with fish consumption rates of subsistence fishers.	Y	N	N	N	N	N	N	N	N	N	N			

106	NTTC	1	PESS, Exposure	N/A	Food other than fish: In the past EPA has stated it would not assess food other than fish because it is the purview of other agencies. EPA would do well to clarify that in this statement "food other than fish" refers to processed or manufactured food products and not the foods represented in tribal lifeways and other subsistence means. Otherwise, EPA is specifically excluding tribal citizens who consume large amounts of land and marine mammal tissue and fats in traditional foods including several species of ungulates, whale and seal, walrus, and sea lion. It also disregards other traditional foods of sea food, migratory birds and their eggs, and certain reptiles. EPA needs to consider these subsistence food sources for which numerous data sources are available from research conducted in the U.S. and other Arctic countries, such as Canada, Greenland and Norway. EPA is a member agency of the White House Cabinet; it is capable of collaborating with its sister agencies that would assess food other than fish, as well as gathering data from such agencies.	Y	N	N	N	N	N	N	N	N	N	N			
107	NTTC	1	PESS, Exposure	N/A	Source-based model is inappropriate for Tribal exposures. In working with OPPT and in preparing the document *Understanding Tribal Exposures to Toxics*, the NTTC requested that OPPT include tribal exposure in their chemicals risk assessments. In response, OPPT staff has requested NTTC to provide the necessary data to consider tribal scenarios. Although some tribes may have data that OPPT is requesting, it became evident that funding for tribal-specific research is needed to provide multiple scenarios for consideration. Chemical-specific monitoring is also needed to determine if TSCA Work Plan chemicals that OPPT is conducting risk assessment on are present in subsistence foods and those resources handled, utilized, or consumed in tribal lifeways. It is unlikely that tribes can generate the necessary analytical data or compile the information OPPT needs to consider exposure pathways for TSCA Work Plan chemicals without specific project funding or technical assistance by EPA to complete tribal risk assessments. Therefore, in addition to addressing OPPT-specific requests for tribal recommendations, NTTC expanded the scope of this report [NTTC 2015] to provide a foundation for requesting studies that could serve OPPT's needs for incorporating tribal-specific data and exposure scenarios into TSCA chemical risk assessments.	Y	N	N	N	N	N	N	N	N	N	N			
108	NTTC	1	PESS, Exposure	N/A	The LifeLine Group, Software Models, and Data Compendiums. The LifeLine Group, Inc. is a US 501(c)(3) non-profit organization that has developed peoplebased probabilistic modeling software that can account for non-standard diets and that has established peer-reviewed compendia of customized dietary files for the American Southwestand Mexican-Influenced diets, Alaska Traditional and Subsistence foods, and First Nations and Inuit in Arctic Canada traditional foods. To identify subpopulations (e.g., children, women, etc.) that are at greater risk, the LifeLine™ Community-Based Assessment Software can use a community's dietary and activity files created with the Dietary Record Generator© and Activity Record Generator© together with the contaminant residue data to present a community-specific exposure and risk assessment. The LifeLine Software can handle a full array of information and values, and describes how exposure and risk are distributed across a population as well as variability in exposure and risk due to day-to-day variation in contaminant or exposure levels. The LifeLine assessment can also examine health effects over the short and longer terms. The software is freely available and with appropriate expertise or assistance, can be used by communities as well as decision-makers at the local, state, provincial and national levels. For instance, for the Compendium of Alaska Traditional and Subsistence Dietary Files©, the LifeLine Group constructed the food consumption database for Alaska Native populations from a diverse array of information about dietary habits, food availability, and economics of the populations for whom there are no detailed food consumption surveys. This and the Dietary Files for the American Southwest™ provide high-quality data that is scientifically accurate, relevant, representative, and quantifiable for uniquely exposed and susceptible subpopulations while reducing the burden of needing chemical-specific data for every single exposure pathway, which is unlikely or nearly impossible for either tribes or EPA to collect. Further information on the relevance, data quality, and other principles to vet the data used in database construction is available at The LifeLine Group's website.	Y	N	N	N	N	N	N	N	N	N	N			
109	NTTC	1	PESS, Exposure	N/A	The durability of tribal environmental exposures may be orders of magnitude higher because Tribal peoples hunt and gather resources locally, then consume and use these local resources—not purchasing them at a grocery store where the meat, produce and other foods might come from any number of different sources and those locations vary over time. Further, for populations in urban areas, there are choices of various fish, meat, and produce in a grocery store, but not so from a subsistence area.	Y	N	N	N	N	N	N	N	N	N	N			
110	NTTC	1	General, PESS, Exposure	N/A	Mitigation by Avoidance or Replacement is Not an Option. When at least half of your diet is derived locally, you cannot stop eating that and switch to other foods. This type of mitigation action used in past risk management strategies, i.e., "don't consume more than X amount in Y timeframe," amounts to an unfunded mandate and forced cultural loss which is documented to lead to a range of societal ills that cause economic impact as well. As Ocampo wrote: Many First Nations [Indigenous People] peoples embrace a shared group identity whose substance is formed not just by one's relationship to the community but also to the land and one's ancestors, which may include plants, animals and other elements of nature. For example, traditional Native Hawai'ians consider the taro, a root staple that nurtures them, a physical ancestor now under their guardianship. Thus, reduction or dispossession of land/loss of stewardship of one's traditional plants and animals is experienced as an alienation or unmooring from the self, and in some communities is directly correlated with suicide (i.e., among the Guarani of Argentina - see Robinson, 2008).	Y	N	N	N	N	N	N	N	N	N	N			
111	NTTC	1	General, PESS	N/A	Whitbeck, Walls, Johnson, Morrisseau, & McDougall (2009) studied depression and historical loss among Indigenous adolescents, reporting that the measures of perceived historical loss and depression were separate but related constructs. Even when controlling for effecting influences such as family factors, discriminatory treatment, and proximal negative life events, an adolescent's perceived historical loss had independent effects on their depressive symptoms. The construct of historical loss is discussed in terms of Indigenous ethnic cleansing: military defeat, relocation to approximate penal colonies, starvation, neglect, forbidden to practice traditional means of survival and spiritual traditions, forced assimilation, children kidnapped and reeducated in settings that ignored kinship patterns, traditional language use punished, and efforts to replace traditional religious beliefs with Christianity, no specific end to government policies of assimilation, and no acknowledgement of ethnic cleansing or apology for it from the U.S. government. Reinschmidt, Attakai, Kahn, Whitewater, & Teufel-Shone (2016) developed the Stories of Resilience Model from interviewing and documenting Urban American Indian Elders' experiences of historical trauma and resilience. "For Indigenous people removed as children to boarding/residential schools or adopted by White families off reservation, this meant being removed from the tribal lands that were closely tied in with culture and traditions, including subsistence practices (farming and hunting), beliefs (traditional spirituality), and values (having respect for oneself and others). Separation from their families led to a loss of contact with relatives, especially elders, who passed on culture and traditions. Family members could no longer teach Native languages or engage children in family activities."	Y	N	N	N	N	N	N	N	N	N	N			

112	NTTC	1	General, PESS	N/A	Despite these historic and generational traumas, tribes have maintained cultural practices and values, and many tribes—but not all—maintained their Indigenous languages, stories, songs, and millennia of history. Thus, contrary to the efforts of colonization, assimilation, and attempts of genocide, research of Indigenous survivors is demonstrating that traditional spirituality, traditional practices, and cultural identity are proven protective factors for Indigenous children and adults. Further, there is accumulating evidence that traditional spirituality and practices are associated with alcohol cessation, are negatively related to depressive symptoms and suicidal behaviors among adults, and that they are associated with academic success, self-esteem, and prosocial behaviors among adolescents. Reinschmidt et al reference work by Kirmayer, Dandeneau, Marshall, Phillips, & Williamson (2011, 2012) supporting that community resilience is compatible with Indigenous values of relationships among people and with the environment. Distinct notions of personhood, where individuals are connected to the land and the environment, shape Indigenous ideas of individual resilience. "Land plays a critical sacrosanct role: it is itself sacred, with tribal-specific meaning, and it is also often directly connected to ritual sacred sites, where ceremonies and obligations are expected to be fulfilled." (Walters, Simoni & Evans-Campbell, 2002.)	Y	N	N	N	N	N	N	N	N	N	N			
113	NTTC	1	General, PESS	N/A	Resilience strategies in the context of the community included being "connected to the community," "involved in local community cultural activities," and "knowing one's Native language" were. Another elder's story demonstrated the connection between personal, family, and community resilience: "think the values that I picked up when I was growing up was making my baskets. That was one of the things that REALLY was good for me… I was taught by my mother and I learned that it really did help me. She …showed me how to prepare to make basket: first to go out and get the plants… I have to talk to the plants. You go up to the plants while you get them, so that it will help you, strengthen you, give you the courage to go on with your life and it's really not just making baskets. It's something that, it's sort of like a sacred secret. So that's what I did. I found out that that's REALLY helped me a lot. Not just making baskets, but keeping up with our tradition, something that our people used to make and use for many things. And also, I sell my baskets a lot so that helped me in many ways…that was my income when I couldn't work…" The Indigenous notion of personhood connects individuals to larger contexts, including family, community, spirituality and history. As described by the elders in the study, and in the literature (Kirmayer et al., 2009, 2012), the Indigenous notion of the self (or person or individual) is one of connectedness. Individual resilience thus must be understood as systemic in nature, because it refers to Indigenous notions of the individual that are characterized by connectedness. In telling their stories, elders talked about people who served as role models for them, about being role models themselves, and about the importance of role models. Most elders fondly remembered their grandparents, parents, or aunts. These relatives imparted knowledge and skills, including gardening, butchering, counseling others, being medicine men, and knowing traditions around birth and death.	Y	N	N	N	N	N	N	N	N	N	N			
114	NTTC	1	General, PESS	N/A	Healing among North American indigenous populations have common themes, shared health beliefs and a unified perspective of bio-psycho-socio-spiritual approaches and traditions, regardless of tribal-specific differences in healing practices, like feathers of different birds, sweat lodge or bonya steam bath, burning a dried herb or burning a fire dish of food. "The culture is the primary vehicle for delivering healing." Bassett, Tsosie, & Nannauck. 2012) "Native diets, ceremonies that greet the seasons and the harvests, and the use of native plants for healing purposes have been used to live to promote health by living in harmony with the earth." Koithan & Farrell (2010). Food from the land gives people life and brings them wellness. (Youth Taking Action, no date (n.d.)) "Alaska Natives have been nourished by foods from the land, air, and water for thousands of years (Alstrom & Johnson, n.d.)34. They have had a lifelong association with these foods, seeking them, harvesting them, cleaning them, preparing them to be eaten or stored, keeping the foods safe from loss of spoilage, and enjoying them as foods. People take great comfort from eating the foods they've grown up with. These foods can be very comfortable to eat in times of illness and healing, and are very rich in the nutrients necessary for good health. Native foods tend to be very good sources of nutrients like protein, iron, Vitamins A, D and E, and low in saturated fats and sugars. Native foods are the heart of culture and health. They provide close ties to the land and the seasons and the environment. Participating in harvesting, preparing, sharing and eating the foods along with others contributes to spiritual well being."	Y	N	N	N	N	N	N	N	N	N	N			
115	NTTC	1	PESS, Exposure	N/A	Disposal is a Condition of Use. Chemicals and/or their byproducts enter the natural environment via disposal of the consumer products. In the absence of considering disposal, EPA will not represent primary exposure pathways for Tribal populations, including the practice of traditional and customary activities, as well as for other populations. Disposal pathway regardless must be considered because contamination of media occurs even with best practice and facilities.	Y	N	N	N	N	N	N	N	N	N	N			
116	NTTC	1	PESS, Exposure	N/A	Activity profiles are not representational. It is known that chlorinated and brominated flame retardants (BFRs) are being released into our environment throughout the world (Bi et al., 2007;35 Kakimoto, Akutsu, Konishi & Tanaka, 200836; Tue et al, 2010;37 Vázquez & Rizo, 2014). Studies such as these include finding brominated flame retardants (BFRs) in multiple biological samples in exposed humans including in the breast milk of mothers living at e-waste recycling sites in China and Vietnam. As noted below, similar practices of openly burning solid waste occur under approved exemption to federal law in Alaska tribal villages, and occur in and near other tribal communities where law enforcement is minimal and underfunded.	Y	N	N	N	N	Y	N	N	N	N	N			
117	NTTC	1	PESS, Exposure	N/A	Not all disposal pathways are in lined landfills where hazardous material and construction and demolition (C&D) waste are disposed of in a separate landfill. There are 207 RCRA Subtitle D municipal waste unlined landfills in Alaska compared to nine lined landfills. The unlined landfills serve approximately half the population of the State and include most construction wastes. There are also occasionally site specific construction and demolition wastes that are universally unlined. Alaska rural landfills are unlined and allow open waste burning—two conditions that in 1976 were prohibited by federal statute for every other community in the United Sates because of the danger to community health, fire safety, and impact on the environment.	Y	N	N	N	N	N	N	N	N	N	N			
118	NTTC	1	PESS, Exposure	N/A	In fact, half of Superfund sites today are the unlined, open burned municipal landfills from the 1960's and 1970's. The lack of liner or emissions treatment means the sites are not designed to accept hazardous wastes. Much of this reason relates to distance from towns to their dump site and from the dump site to community drinking water sources. Wastes form leachate, which drains to drinking and subsistence water. About one third of Alaska offroad village dumpsites are within one quarter mile of a drinking water source, and about half flood each year. If wastes aren't discarded at the landfill, they are burned untreated and form toxic waste smoke and emissions, which is smelled in and around homes in about 80% of towns. About one fourth of these communities are breathing toxic emissions from their community's dumpsite at home, in town, every day for hours. While not many health studies have been carried out specific to villages, in 2002, with the same conditions existing as they still are today, Zender Environmental conducted a retrospective study in four villages and found that people who visited their dump were 2 to almost 4 times more likely to experience faintness, fever, vomiting, stomach pain, ear and eye irritation, headache, and/or numbness (Gilbreath, Zender & Kass, n.d.). The more often people visited the dump, the more likely they were to experience the symptoms. In a 2006 study by Gilbreath and Kass, Alaska Native Village dump sites without a way to separate and backhaul their hazardous wastes were found to present increased risks for lower birth weight, shorter gestation, and 4.3 times greater risk for several types of birth defects. It should be noted that multiple states across the country permit unlined construction and demolition (C &D) landfills under RCRA. These C & D landfills are nearly always in rural areas, where the vast bulk of tribes reside. Further, checkerboard jurisdiction on reservations means that open dumping by contractors and the general public occurs regularly.	Y	N	N	N	N	N	N	N	N	N	N			

119	NTTC		1	PESS, Exposure	N/A	In tribal communities and in rural and low-income communities across the country, citizens are recycling and recovering consumer products, like removing useable parts from dead vehicles, taking home the free sofa outside the landfill fence, fishing in the dikes and ditches. A study that could be potentially used as a surrogate for these types of activities was conducted by Athanasiadou, Cuadra, Marsh, Bergman, & Jakobsson (2008) where they looked at exposure to PBDEs and bioaccumulative hydroxylated PBDE metabolites in young people, including children, from Managua, Nicaragua. [abstract from Athanasiadou et al] Stephenson and Harrad published their critical review of BFRs emissions from waste soft furnishings in 2014 which contained their noteworthy recommendation that waste soft furnishings be treated with the same concern as e-waste containing BFRs. [excerpt from Stephenson and Harrad]	Y	N	N	N	N	N	N	N	N	N	N			
120	NTTC		1	PESS, Exposure	N/A	Leachate from Unlined Landfills. Waterborne –In rural areas, wastewater may go through primary treatment only, then is discharged to surrounding water bodies. But a wide range of chemicals has been found even in secondary treatment of wastewater from urban POTW's. Only in the last five years or less, have the number and type of chemicals being sampled expanded to include a wider range of chemicals of concern. [summaries regarding determination of various chemicals found in wastewaters from various locations]	Y	N	N	N	N	N	N	N	N	N	N			
121	NTTC		1	PESS, Exposure	N/A	Air Emissions from Open Waste Burning. This study investigated the occurrence of polychlorinated biphenyls (PCBs), and several additive brominated flame retardants (BFRs) in indoor dust and air from two Vietnamese informal e-waste recycling sites (EWRSs) and an urban site in order to assess the relevance of these media for human exposure (Tue et al. 2013). 50 The levels of PBDEs, HBCD, 1,2-bis-(2,4,6-tribromophenoxy)ethane (BTBPE) and decabromodiphenyl ethane (DBDPE) in settled house dust from the EWRSs (130-12,000, 5.4-400, 5.2-620 and 31-1400 ng g(-1), respectively) were significantly higher than in urban house dust but the levels of PCBs (4.8-320 ng g(-1)) were not higher. The levels of PCBs and PBDEs in air at e-waste recycling houses (1000-1800 and 620-720 pg m(-3), respectively), determined using passive sampling, were also higher compared with non-e-waste houses. The composition of BFRs in EWRS samples suggests the influence from high-temperature processes and occurrence of waste materials containing older BFR formulations. Results of daily intake estimation for e-waste recycling workers are in good agreement with the accumulation patterns previously observed in human milk and indicate that dust ingestion contributes a large portion of the PBDE intake (60%-88%), and air inhalation to the low-chlorinated PCB intake (>80% for triCBs) due to their high levels in dust and air, respectively.	Y	N	N	N	N	Y	N	N	N	N	N			
122	NTTC		1	PESS, Exposure	N/A	Further investigation of both indoor dust and air as the exposure media for other ewaste recycling-related contaminants and assessment of health risk associated with exposure to these contaminant mixtures is necessary.	Y	N	N	N	N	N	N	N	N	N	N			
123	NTTC		1	PESS, Exposure	N/A	The open burning of waste, whether at individual residences, businesses, or dump sites, is a large source of air pollutants (Wiedinmyer, Yokelson, & Gullett, 2014). These emissions, however, are not included in many current emission inventories used for chemistry and climate modeling applications. This paper presented the first comprehensive and consistent estimates of the global emissions of greenhouse gases, particulate matter, reactive trace gases, and toxic compounds from open waste burning. Global emissions of CO2 from open waste burning are relatively small compared to total anthropogenic CO2; however, regional CO2 emissions, particularly in many developing countries in Asia and Africa, are substantial. Further, emissions of reactive trace gases and particulate matter from open waste burning are more significant on regional scales. For example, the emissions of PM10 from open domestic waste burning in China is equivalent to 22% of China's total reported anthropogenic PM10 emissions. The results of the emissions model presented here suggest that emissions of many air pollutants are significantly underestimated in current inventories because open waste burning is not included, consistent with studies that compare model results with available observations.	Y	N	N	N	N	N	N	N	N	N	N			
124	NTTC		1	General, Exposure	N/A	Disposal pathway regardless must be considered because contamination of media occurs even with best practice and facilities.	Y	N	N	N	N	N	N	N	N	N	N			
125	NTTC		1	General, Exposure	N/A	Throughout Asia, non-PBDE BFRs like HBCD, have extensively polluted coastal waters (Isobe, Ogawa, Ramu, Sudaryanto, & Tanabe 2012). They used mussels as a bioindicator, as did studies by the US National Oceanic & Atmospheric Administration of coastal US waters (Isobe et al., 2012), Isobe et al were studying the presence of BFRs, the range throughout Asia, and the levels of concentrations. Among the three HBCD diastereoisomers, α-HBCD was the dominant isomer followed by γ- and β-HBCDs. Concentrations of HBCDs and DBDPE in mussels from Japan and Korea were higher compared to those from the other Asian countries, indicating extensive usage of these non-PBDE BFRs in Japan and Korea. Higher levels of HBCDs and DBDPE than PBDEs were detected in some mussel samples from Japan. The results suggest that environmental pollution by non-PBDE BFRs, especially HBCDs in Japan, is ubiquitous. This study provides baseline information on the contamination status of these non-PBDE BFRs in the coastal waters of Asia. More than 1,500 construction and demolition debris (CDD) landfills operate in the United States (U.S.), and U.S. federal regulations do not require containment features such as low-permeability liners and leachate collection systems for these facilities (Powell, Jain, Smith, Townsend, & Tolaymatl; 2015). Here we evaluate groundwater quality from samples collected in groundwater monitoring networks at 91 unlined, permitted CDD landfills in Florida, U.S. A total of 460,504 groundwater sample results were analyzed, with a median of 10 years of quarterly or semiannual monitoring data per site including more than 400 different chemical constituents. Downgradient concentrations of total dissolved solids, sulfate, chloride, iron, ammonia-nitrogen, and aluminum were greater than upgradient concentrations ($p < 0.05$). At downgradient wells where sulfate concentrations were greater than 150 mg/L (approximately 10% of the maximum dissolved sulfate concentration in water, which suggests the presence of leachate from the landfill), iron and arsenic were detected in 91% and 43% of samples, with median concentrations of 1,900 μg/L and 11 μg/L, respectively. These results show that although health-based standards can be exceeded at unlined CDD landfills, the magnitude of detected chemical concentrations is generally small and reflective of leached minerals from components (wood, concrete, and gypsum drywall) that comprise the bulk of discarded CDD by mass.	N	N	N	N	N	Y	N	N	N	N	N			
126	NTTC		1	Human Health	N/A	Prior to the Lautenberg Act amending TSCA, risk assessments have not accounted for existing body burden suite of chemicals, which is also not addressed in either the Human Health Risk Assessment Guidelines nor the Cumulative Risk Guidelines listed on the EPA web sites. Tribal people are especially exposed to larger volumes of chemicals due to their tribal lifeways and their geographic locations in relation to manufacturing and pollutant deposition. Along with higher amounts of toxin exposure and bioaccumulation, there is greater risk of the suite of chemicals interacting and causing health effects not accounted for by single-chemical risk assessments. NTTC continues to urge EPA to move beyond just cancer risk or only toxicity, and assess more concerning endocrine disrupting health effects as levels of risk from known endocrine disrupter chemicals (EDCs). These EDCs are particularly dangerous and not adequately assessed in the most recent risk scenarios.	Y	N	N	N	N	N	N	N	N	N	N			
127	NTTC		1	General	N/A	In August 2015, EPA published for public comment its TSCA Work Plan Chemical problem formulation and initial assessment documents for the three flame retardant clusters Brominated Bisphenol A (TBBPA), Chlorinated Phosphate Esters (CPE), and Cyclic Aliphatic Bromides (HBCD) (USEPA 2015c). In response NTTC provided written comments to that docket which we recapture here in relevance to problem formulation and risk evaluation under the amended TSCA.	N	N	N	N	N	N	Y	N	N	N	N			
128	NTTC		1	General, Exposure	N/A	NTTC appreciates EPA's inclusion of fish consumption by subsistence fishers and their children when evaluating exposure pathways for CPE. We specifically highlight EPA's commitment to account for the high-end fish consumption of subsistence fishers—including pregnant women, children and adults—the majority of whom are the tribal population.	N	N	N	N	N	N	Y	N	N	N	N			
129	NTTC		1	Human Health	N/A	NTTC agrees with the need to evaluate the hazard endpoints that go beyond cancer risk and include target organ effects, reproductive and developmental effects, and neurotoxicity (U.S. EPA 2015d, p. 32, 34).	N	N	N	N	N	N	Y	N	N	N	N			

130	NTTC	1	Human Health, Exposure	N/A	In CPE Problem Formulation of 2015, EPA stated it would exclude from further assessment the exposures of birds, terrestrial wildlife, or sediment-dwelling organisms as well as food other than fish. In our comments, NTTC noted its disagreement with EPA's decision as these exclusions fail to account for the subsistence diets of tribal populations, which include these species and other resources that consume these species. In the CPE Problem Formulation, EPA noted that [m]onitoring studies have reported the detection of TCEP in aquatic species, mammalian species, herring gull eggs and pine needles. ...these materials are likely bioavailable and could be observed in a biological matrix." (U.S. EPA 2015d, p. 22). The referenced studies showed detection of CPEs in the breast milk of women in Sweden, Asia, Japan, the Philippines, and Vietnam. These data demonstrate the need for consideration of the natural environment and food resources of tribal populations. Aquatic species, mammalian species and gull eggs are all natural resources upon which tribal populations subsist.	N	N	N	N	N	N	Y	N	N	N	N			
131	NTTC	1	Fate, Exposure	N/A	Yu et al. (2016) compiled and reviewed existing literature on the contamination status of BFRs in abiotic and biotic environments in China, including polybrominated diphenyl ethers (PBDEs), hexabromocyclododecane, tetrabromobisphenol A and new BFRs. 58 Temporal trends were also summarized and evaluated. Based on this review, it has been concluded that (1) high concentrations of PBDEs were generally related to the e-waste disposal processing, while the spatial distribution pattern of other BFRs was not necessarily in accordance with this; (2) extremely high concentrations of BFRs in indoor dust emphasized the importance of indoor contamination to human body burdens, while more work need to be done to confirm its contribution; (3) PBDEs in electronics dismantling workers were higher compared to the general population, indicating the occupational exposure should be of particular concern; (4) more data are now becoming available for BFRs in aquatic and terrestrial organisms not previously studied, while studies that consider the occurrence of BFRs in organisms of different trophic levels are still of urgent need for evaluating the fate of BFRs in the food web; and (5) limited data showed a decreasing trend for PBDEs, while more data on time trends of BFR contamination in various matrices and locations are still needed before the impact of regulation of BFRs can be assessed.	N	N	N	N	N	N	Y	N	N	N	N			
132	NTTC	1	PESS, Exposure	N/A	During problem formulation of HBCD, EPA identified inhalation, dermal and lifetime exposure assessments as data gaps that add uncertainty to EPA's risk assessment of HBCD. NTTC continues to maintain that EPA must include tribal populations in its plans to "conduct additional risk analysis on potential worker, general population, consumer and environmental exposures under the TSCA Existing Chemicals Program" (U.S. EPA, 2015e, p. 11).	N	N	N	N	N	N	Y	N	N	N	N			
133	NTTC	1	PESS, Exposure	N/A	EPA noted that HBCD is a persistent pollutant in environmental media, expected to occur primarily as particulates, which may undergo long range transport, and is highly bioaccumulative with measured fish Bioconcentration factor values of greater than 18,000 (U.S. EPA, 2015e, p. 22). Given this, EPA must consider the impact of consumption by tribal citizens who live in geographic ranges where the majority of industrial-sourced particulates are deposited, who rely on traditional foods of fish and marine mammals which bioaccumulate toxins via fish and algae consumption. Further, on page 24 of the HBCD Problem Formulation, EPA referenced data of HBCD measured in the blubber and liver of various marine mammals; both of these tissues are a staple, consumed in large quantities, in Arctic tribal citizens' diets (U.S. EPA, 2015e, p. 76). Then, regarding bioaccumulation, EPA referenced studies that note the widespread detection and high levels of HBCD in aquatic and terrestrial organisms: invertebrates, fish, birds and their eggs, and marine mammals, all of which are traditional food resources of tribes. Finally, HBCD was detected in breast milk, adipose tissue, blood, and both maternal and umbilical serum (U.S. EPA, 2015e, p. 85). These references to EPA's own work highlights NTTC's principle that EPA must account for tribal populations, especially sensitive infant and child populations, in its risk evaluation of HBCD.	N	N	N	N	N	N	Y	N	N	N	N			
134	NTTC	1	PESS, Exposure	N/A	NTTC supports the EPA's decision for comprehensive studies for many endpoints for all cluster members of the TBB/TBPH cluster. NTTC also supports the EPA's statement of need for comprehensive studies on bioaccumulation of all brominated phthalate cluster (BPC) chemicals. Considering persistence and toxicity data on other brominated flame retardants, bioaccumulation and persistence data are extremely necessary. With the potential for acute and chronic toxicity, reproductive toxicity, and negative health effects on fetal development and endocrine disruption, it is alarming that the U.S. allows continued use of BPC chemicals. NTTC maintains its position that EPA must also consider chemical body burden, in addition to testing all cluster members individually and quantifying major degradation products. With suggested potential of long-term exposure of TBB/TBPH to wildlife, EPA stated that "chronic testing is recommended to address those organisms likely exposed in order to characterize potential population level effects"; and that suggested potential of "exposure and uptake by organisms present in water bodies including aquatic plants thus, hazard and bioaccumulation characterization is needed for these organisms" (U.S. EPA, 2015f, p. 39).60 (TBB/TBPH PF and DNA, 08/158, pp. 39) Therefore, NTTC reiterates that EPA must then also consider the effect of subsistence foods and traditional natural resources on the tribal population. This includes high-level consumption of marine mammals, such as whale, seal, walrus, and sea lion; fish and shellfish, such as salmon, herring, halibut, crab, and mussels; avian species such as duck, geese, and gull; and wildlife such as moose, deer, caribou, and elk.	N	N	N	N	N	N	Y	N	N	N	N			
135	NTTC	1	Exposure	N/A	Since the problem formulations noted above were released in 2015, NTTC has further researched these chemicals in commerce. Brominated flame retardants are found to be a frequent and at times high concentration of indoor dust in houses, apartments, daycare centers, and primary schools, and of the highest concentrations in North America and Europe (Malliari & Kalantzi, 2017). 61 "Results from the studies showed that dust ingestion was the dominant exposure pathway for most studied BFRs compared to indoor air inhalation and dermal contact, especially for infants and toddlers who have higher exposures than older children."	N	N	N	N	N	N	Y	N	N	N	N			
136	NTTC	1	Human Health	N/A	HBCD Toxicity testing has detected reproductive, developmental and behavioral effects in animals where exposures are sufficient (Marvin et al. 2011). Recent toxicological advances include a better mechanistic understanding of how HBCD can interfere with the hypothalamicpituitary-thyroid axis, affect normal development, and impact the central nervous system defects.	N	N	N	N	N	N	Y	N	N	N	N			
137	NTTC	1	Human Health, Exposure	N/A	Fish represents source of nutrients and major dietary vehicle of lipophilic persistent contaminants (Maranghi 2013). The study compared the effects of two legacy and two emerging fish pollutants (Hexabromocyclododecane HBCD; 2,2',4,4'-Tetrabromodiphenyl ether BDE-47; 2,2',4,4',5,5'-Hexachlorobiphenyl PCB-153; 2,3,7,8-Tetrachlorodibenzo-p-doxin TCDD) in juvenile female mice exposed through a salmon based rodent diet for 28 days (dietary doses: HBCD 199 mg/kg bw/day; BDE-47 450 μg/kg bw/day; PCB-153 195 μg/kg bw/day; TCDD 90 ng/kg bw/day). Dose levels were comparable to previously reported developmental Lowest Observed Adverse Effect Levels. None of the treatments elicited signs of overt toxicity, but HBCD increased relative liver weight. All compounds caused changes in liver, thymus and thyroid; spleen was affected by BDE-47 and PCB-153; no effects were seen in uterus and adrenals. Strongest effects in thyroid follicles were elicited by PCB-153, in thymus and liver by BDE-47. HBCD and BDE-47 induced liver fatty changes, but appeared to be less potent in the other tissues. HBCD, BDE-47 and TCDD increased serum testosterone levels and the testosterone/estradiol ratio, suggesting a potential involvement of pathways related to sex steroid biosynthesis and/or metabolism. The results support the role of toxicological studies on juvenile rodents in the hazard characterization of chemicals, due to endocrine and/or immune effects.	N	N	N	N	N	N	Y	N	N	N	N			

138	NTTC	1	PESS, Exposure	N/A	Tribal people's socioeconomic status and customary lifeways support a representative subpopulation role. Some aspects of Tribal people's lifestyle are shared by non-Tribal peoples living in the same or similar geographic area, and/or of similar socio-economic levels. These lifestyle aspects are not necessarily traditional in the sense of purposeful transfer between generations, and they often do not have the same weight of value, or a negative value. But their characteristics are still critical to ensure that risk assessments are relevant to tribal peoples. By making profiles that reflect these aspects of Tribal people's lifestyle, risks of other subgroups that also were not represented can be more accurately assessed as well. The standard of relevance dictates that the risk assessment models used are applicable to the population being examined. As noted above, tribal lifeways result in people interacting with and consuming resources from the ecological environment more frequently and in greater volumes than the general population, and in some cases, what would orders of magnitude differences.	Y	N	N	N	N	N	N	N	N	N	N			
139	NTTC	1	Fate, PESS, Exposure	N/A	Extensive research indicates significantly concerning characteristics of brominated flame retardants (BFRs). -BFRs are extensively present in environmental and biota samples worldwide, -BFRs are persistent, bioaccumulative, and biomagnified, and -BFRs have high potential toxicity to both ecological environment and human health. Thus BFRs have an even greater potential toxicity to those who more frequently interact with and consume resources from the ecological environment. This is supported by Yu et al. (2016), Wang et al. (2010).	N	N	N	N	N	N	Y	N	N	N	N			
140	NTTC	1	Fate, PESS, Exposure	N/A	The particular relevance to tribal lifeways as representative of potentially exposed and susceptible subpopulations is especially demonstrated in Yu et al (2016) who, just two years ago, published their review of then existing literature on the contamination status of BFRs in abiotic and biotic environments in China, including polybrominated diphenyl ethers (PBDEs), HBCD, tetrabromobisphenol A (TBBPA), and newer brominated flame retardants (BFRs). Temporal trends were also summarized and evaluated. They concluded that (1) high concentrations of PBDEs were generally related to the e-waste disposal processing, while the spatial distribution pattern of other BFRs was not necessarily in accordance with this; (2) extremely high concentrations of BFRs in indoor dust emphasized the importance of indoor contamination to human body burdens, while more work need to be done to confirm its contribution;(3) PBDEs in electronics dismantling workers were higher compared to the general population, indicating the occupational exposure should be of particular concern; (4) more data are now becoming available for BFRs in aquatic and terrestrial organisms not previously studied, while studies that consider the occurrence of BFRs in organisms of different trophic levels are still of urgent need for evaluating the fate of BFRs in the food web; and (5) limited data showed a decreasing trend for PBDEs, while more data on time trends of BFR contamination in various matrices and locations are still needed before the impact of regulation of BFRs can be assessed.	N	N	N	N	N	N	Y	N	N	N	N			
141	NTTC	1	Fate, PESS, Exposure	N/A	The findings by Wang et al. (2010) are alarming when considered in relation to tribal lifeways and the disposal of electronics in unlined landfills or dumpsites and by open burning. Brominated flame retardants (BFRs) in house dust from the electronic waste (ewaste) recycling and urban areas of South China showed that PBDE levels were comparable to the values found in North America. ...The distinct dust BFR profiles observed in the two studied areas were reflective of activities in these areas (electronics industry vs. e-waste recycling). The estimated daily intakes (EDIs) via house dust were much higher than those via other indoor pathways (air, fish, human milk, and toys). Despite the potentially low deleterious risk of PBDE exposure via house dust as suggested by the hazard quotients, this exposure pathway should be of great concern because of the higher BFR exposures for children and the presence of other BFRs (such as DBDPE) which have not yet been fully investigated. Housing-related exposures, for example. Used furniture and other items containing flame retardants, are gifted to others, purchased at thrift stores or yard sales, and found as free items on sidewalks, roadsides, and at the landfill. Furniture is kept longer than in urban and general populations, often well-passed typical time ranges and simply covered with sheets, blankets or other fabrics. Housing structures are older and smaller, similar to low-income and rural areas, and do not contain air conditioning systems, do not contain air filters, and residents rely on open windows and doors for summer cooling and for venting when cooking and cleaning. Dusting and vacuuming equipment is typically older, lesser quality, or non-existent. Inhalation and ingestion are major exposure pathways and EPA must account for these situations and factors when considering risk.	N	N	N	N	N	N	Y	N	N	N	N			
142	NTTC	1	Fate, PESS, Exposure	N/A	Public infrastructure: The tribal communities we discuss live with significantly outdated public infrastructure, e.g., private wells for drinking water, unplumbed homes, open dumping, kids playing around open dumps. They and others in rural America experience lifestyles much different from the urban centers: recreational swimming in natural water bodies, produce gardening and farming, living near open dumping, unpaved road dust, Arctic entry ways, living all or most of lifetime where they were raised, potlucks and social gatherings, sharing of harvested, grown, and gathered foods. For rural Alaska villages, drinking water, showers, and laundry are accessed at the public watering point, often called the washeteria, where wastewater is handled with only primary treatment. Schreder & La Guardia (2014) studied levels of flame retardants in residential house dust and laundry wastewater as a transport pathway from homes to the outdoor environment in communities near the Columbia River in Washington state (WA), accounting for influent and effluent from two wastewater treatment plants (WWTPs) servicing these communities. Of the 21 brominated and chlorinated compounds, including HBCD, detected in dust, 18 were also detected in laundry wastewater. Comparison of flame retardant levels in WWTP influents to estimates based on laundry wastewater levels indicated that laundry wastewater may be the primary source to these WWTPs.	N	N	N	N	N	N	Y	N	N	N	N			
143	NTTC	1	Fate, PESS, Exposure	N/A	Lack of options in lifestyle. Food is gathered from land and waters locally and regionally. In the 2014 analysis update on subsistence in Alaska, rural residents harvested between 145 and 405 pounds per person per year of wild foods (Fall & Wolfe, 2016).67 The average per person per year amount was about 275 pounds for rural residents versus 19 for urban residents. That was about 0.75 pounds a day per person for rural residents versus 0.05 for urban residents. Costs of store items in Alaska villages and rural areas is prohibitive, often four or more times more expensive than in urban areas, so in general, there are less alternatives to food gathered. There are significantly fewer employment opportunities and higher costs for heating fuel, vehicle fuel, and household basic necessities due to added on cost of shipping items to village. Without incorporating these general profiles, the proposed problem formulations are not relevant to Tribal peoples, a susceptible subpopulation. La Guardia, Hale, Harvey, Mainor, Ciparis (2012) studied in-situ accumulation of HBCD, PBDEs, and several alternative flame-retardants in the bivalve and gastropod. While they found that several alternative brominated flameretardants (BFRs) were being detected in the environment, they noted that contaminant bioavailability is influenced by the organisms' ecology (i.e., route of uptake) and in situ environmental factors. We observed that the filter-feeding bivalve (Corbicula fluminea) and grazing gastropod (Elimia proxima), collected downstream from a textile manufacturing outfall. Maximum levels of total hexabromocyclododecane diastereomers (ΣHBCDs) and those of polybrominated diphenyl ethers (ΣPBDEs) were among the highest reported to date worldwide. While BDE-209 was once thought to be nonbioavailable and resistant to degradation, it was the dominant BFR present and likely debromination products were detected. Contributions of α- and β-HBCD were higher in tissues than sediments, consistent with γ-HBCD bioisomerization. Mollusk bioaccumulation factors were similar between HBCD and PBDEs with 4 to 6 bromines, but factors for TBB, TBPH, and BTBPE were lower. Despite different feeding strategies, the bivalves and gastropods exhibited similar BFR water and sediment accumulation factors.	N	N	N	N	N	N	Y	N	N	N	N			

144	NTTC		1	Fate, PESS, Exposure	N/A	In consideration of BFRs effect on flora, for example, Wu, Huang & Zhang (2016) investigation of the accumulation and phytotoxicity of technical hexabromocyclododecane (HBCD) in maize, using young seedlings exposed to solutions of technical HBCD at different concentrations. The results demonstrate HBCD accumulation in both the roots and shoots of the plant, HBCD causing DNA damage, and variances between HBCD diastereoisomers. The uptake kinetics showed that the HBCD concentration reached an apparent equilibrium within 96hr, and the accumulation was much higher in roots than in shoots. HBCD accumulation in maize had a positive linear correlation with the exposure concentration. The accumulation of different diastereoisomers followed the order γ-HBCD>β-HBCD>α-HBCD. Compared with their proportions in the technical HBCD exposure solution, the diastereoisomer contribution increased for β-HBCD and decreased for γ-HBCD in both maize roots and shoots with exposure time, whereas the contribution of α-HBCD increased in roots and decreased in shoots throughout the experimental period. These results suggest the diastereomer-specific accumulation and translocation of HBCD in maize. Inhibitory effects of HBCD on the early development of maize followed the order of germination rate>root biomass≥root elongation>shoot biomass≥shoot elongation. Hydroxyl radical (OH) and histone H2AX phosphorylation (γ-H2AX) were induced in maize by HBCD exposure, indicative of the generation of oxidative stress and DNA double-strand breaks in maize. An OH scavenger inhibited the expression of γ-H2AX foci in both maize roots and shoots, which suggests the involvement of OH generation in the HBCD-induced DNA damage. The results of this study will offer useful information for a more comprehensive assessment of the environmental behavior and toxicity of technical HBCD.	N	N	N	N	N	N	Y	N	N	N	N			
145	NTTC		1	Fate, PESS, Exposure	N/A	Several studies in the last few years have built on data analysis of BFRs in aquatic and terrestrial species. Sun et al. (2018) measured α-, β-, and γ-HBCDs in three freshwater fish—mud carp, tilapia, and plecostomus—from rivers and an electronic waste (ewaste) recycling site in Pearl River Delta, South China. [Summaries from multiple studies]	N	N	N	N	N	N	Y	N	N	N	N			
146	NTTC		1	General, PESS, Exposure	N/A	With Tribes as a representative population for greater environmental media exposure risk, any resultant action levels will not only protect tribes and the general population, but the ethnic, minority, and rural population groups that may be at higher risk due to their customary lifestyle and activities and/or traditional practices. Fishing illustrates this point. Fishing is a universal practice for Alaska Tribes, potential exposure via ingestion of contaminated fish is higher due to higher consumption, as is potential exposure via inhalation through smoking fish, and other heat preparation methods particularly with poor indoor ventilation, via potential absorption when fishing and preparing a greater amount of fish, via non-dilution of contaminated fish with fish from another location due to unavailability of store-bought fish, via particular practices associated with fishing, which may include gathering greens and using untreated water near the fishing spot, etc. Also, the full Tribal population – from infant to elder, disabled, single parents with small children and relative living outside the village – is exposed due to sharing of fish. This is a magnified representation of the Alaska population as a whole, particularly the rural population, which tend to fish for, and share and eat fish like salmon, at a much greater rate than their counterparts in the contiguous states. The same can be said for exposure to contaminated "game meats", marine mammals, berries, water and other environment sources due to customary food resources and recreational activities. With Tribes as representative, the full Alaska population is protected.	Y	N	N	N	N	N	N	N	N	N	N			
147	NTTC		1	General, PESS, Human Health	N/A	The sociocultural consequences to Tribal communities of overexposure to chemicals are as significant, or more significant, compared to the consequences to other groups. The small population size, high-context, and group-oriented nature of Tribal populations translates to substantial impact on health and well-being when a Tribal member is negatively affected by chemical exposures. For example elders are a significant resource in their community and fill multiple roles. Teachers of cultural values and mores for their community including other older adults that are younger than the elder in addition to children and teens. It is well documented that tribal people's socio-cultural knowledge base is more internalized and is not adequately learned via verbal or written instructions. It must be acquired over a lifetime of experiencing the day-to-day contexts of being a tribal person and relating with elders that have fully acquired the knowledge in their time by being with generations past. Sources of historical information shared with their community including other older adults that are younger than the elder in addition to children and teens. Leaders whose experience provides stability and experience to the tribal council and in consultations with government agencies. Caretakers for extended family members, providing unpaid childcare. A grandmother who develops cancer will not be able to care for her grandchildren, parents may miss work resulting in job or income loss, or children may miss a critical mentor role or be injured because they are left alone.	Y	N	N	N	N	N	N	N	N	N	N			
148	NTTC		1	General, PESS, Human Health	N/A	Impacts to societal health and well-being contribute to disproportionate health and socioeconomic indicators. E.g., exposure to a certain chemical affects childhood brain development, causing neuro-developmental delays, which are compounded as the child progresses through school and Tribal populations suffer from low high school and college graduation rates.	Y	N	N	N	N	N	N	N	N	N	N			
149	NTTC		1	General, PESS, Exposure	N/A	While NTTC recognizes that part of EPA's risk assessment process is collecting existing data on the chemicals in question, asking tribes to fill this data gap is unreasonable. EPA must provide funding before starting the process (at least more than one year prior) to request tribes gather information. Specifically, sampling within tribal homes in high-risk areas would provide valuable data to further complete risk assessments accounting for high-risk, vulnerable tribal populations. EPA must take into account widespread backyard open burning and open burning at both municipal and construction & demolition landfills. Tribal and other rural citizens are exposed to chemicals in commerce via this pathway, including HBCD. These types of burning are prevalent in underserved tribal communities on reservations in the U.S. and other rural lands, including nearly every community in the State of Alaska. These communities rarely have proper burn units nor appropriate safety protocols to prevent residents' inhalation.	Y	N	N	N	N	N	N	N	N	N	N			
150	NTTC		1	General, PESS, Exposure	N/A	Again, regarding fish consumption and the rate referenced above, in relation to population scenarios, the tribal population scenario is the most appropriate to use for risk assessments by EPA, because their rules indicate that they are to protect the population of highest risk. As identified in the 2015 problem formulation for the HBCD cluster, EPA must use fish consumption rates for subsistence fishers in aggregate exposure for those who rely heavily on locally sourced fish.	Y	N	N	N	N	N	N	N	N	N	N			
151	NTTC		1	General, PESS, Exposure	N/A	It is imperative that EPA consider potential cumulative exposure—including multiple chemical exposure—in these risk assessments because it is an on-going void in implementing environmental justice policies. This is a significant problem that EPA is not considering cumulative exposure in the risk assessment process at this time. It is an environmental justice issue affecting tribes, who rely heavily on high volumes of fish and aquatic mammals for half or more of their diet. Additionally, a large percentage of American Indian and Alaska Native communities are at or below the poverty level. This translates to lower replacement cycles of furniture, toys, clothing etc. from those with higher toxicities to more recently manufactured items of lower toxicities. For example, although PCB is no longer manufactured, studies have detected it in Puget Sound tissue sample monitoring. EPA must also look at wastewater outside of only the Toxics Release Inventory, which does not account for small local government facilities like unlined but permitted landfills, unpermitted landfills, open dumps, and open dump and backyard burning. As the Council has previously discussed with EPA, the stovepiped processes of EPA fails in protecting tribes from exposures to chemical in commerce.	Y	N	N	N	N	N	N	N	N	N	N			

152	NTTC	1	PESS, Exposure	N/A	Most states have developed fish consumption advisories to protect residents from toxins in fish species known to bioaccumulate contaminants. One particular challenge that has been expressed by state fish advisory programs is communicating fish advisory information to ethnic or immigrant populations who do not speak English and are difficult to reach via fish advisory communication methods targeted toward the broader public. Ethnic or immigrant populations are specifically at risk due to their predominantly urban fishing locations that of contaminants than species typically consumed by sport fisherman (due to benthic feeding habits or tolerance to live in polluted waters). EPA maintains a compendium of fish advisory technical information including contacts for state and Tribal fish consumption advisory programs managers at its website at https://www.epa.gov/fishtech. In addition, EPA supports a fish advisory program manager listserv to promote sharing of fish consumption advisory technical information among state and Tribal fish advisory program managers and EPA. The EPA contact for this program is Sharon Frey (Frey.Sharon@epa.gov or 202-566-1480) and she should be contacted to assist with compiling existing consumption and exposure information for ethnic or immigrant subsistence fishers residing in urban areas.	Y	N	N	N	N	N	N	N	N	N	N			
153	BASF_CommentJuly6 2018	1	Exposure	N/A	BASF appreciates the opportunity to add information to Docket No.: EPA-HQ-OPPT-2016-0723 in response to the EPA document dated May 2018 "Problem Formulation of the Risk Evaluation for 1,4-Dioxane". BASF would like to make you aware that in April 2018 we informed our customers that BASF will cease the manufacturing 1,4-Dioxane (CAS 123-91-1) from our manufacturing location in Zachary LA USA by the end of 2018. We are currently in the process of qualifying our current customers to a source of imported material from BASF SE based in Ludwigshafen Germany. This decision to cease manufacturing of 1,4-Dioxane in the US is not a result of the EPA risk assessment activity - rather one based on economics and the declining sales and use of 1,4- Dioxane in North America.	N	N	Y	N	N	N	N	N	N	N	N			
154	BASF_CommentJuly6 2018	1	Exposure	N/A	We provide this information to EPA to assist you in prioritizing your assessment activities. Since BASF Corporation, as the sole producer of 1,4-Dioxane in the US, will no longer be manufacturing, you can remove any US manufacturing employee exposure risk assessment activities from your work plan. As mentioned, we may replace this with import of bulk material that will need to be repackaged to smaller quantities which may change your assessment activities. We felt this information may be of value for your continued assessment of 1,4- Dioxane and its potential exposures.	N	N	Y	N	N	N	N	N	N	N	N			
155	EPN_CommentJuly31 2018	1	RegNex	N/A	The Environmental Protection Network (EPN) is providing the following comments on the problem formulations for asbestos, HBCD and carbon tetrachloride, which we find are setting improper precedents for future chemical risk evaluations under the new Chemical Safety Act amendment to TSCA. The final rule states that EPA is given discretion to determine the conditions of use that it will address in its evaluation of a priority chemical, "in order to ensure the agency's focus is on the conditions of use that raise the greatest potential for risk." The final rule mentions excluding de minimis conditions of use or conditions of use that have been adequately addressed by another regulatory agency. The final rule also states that while the statute is ambiguous as to whether the conditions of use should include legacy uses, "in a particular risk evaluation, EPA may consider background exposures from legacy use, associated disposal and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses."	Y	N	N	N	N	Y	Y	N	N	N	Y			
156	EPN_CommentJuly31 2018	1	Exposure, PESS	N/A	In contrast to this final rule, the Chemical Safety Act is clear that EPA must identify and evaluate risks resulting from all intended or reasonably foreseen, as well as known conditions of use of a chemical substance. EPA is required to make a determination on the chemical substance as to whether it presents an unreasonable risk of injury to health or the environment without consideration of costs or other non-risk factors due to a single use or any combination of uses. If an unreasonable risk is found, TSCA provides EPA with a broad set of authorities to deploy actions that fully eliminate the unreasonable risk. The timing, frequency, location and duration of all exposures and their magnitude at a given point in time and space are key to determining unreasonable risk for susceptible subpopulations such as infants, pregnant women, the elderly, workers and disproportionately exposed communities. TSCA requires two kinds of risk assessment, one for a single or sentinel exposure to evaluate acute toxic effects and one for aggregate exposure of co-occurring sources to evaluate chronic toxic effects. Since all 10 chemicals addressed in these first problem formulations have chronic toxic effects, a comprehensive aggregate assessment of all co-occurring exposures is critical since excluding even one pathway will underestimate cancer and non-cancer effects.	Y	N	N	N	N	N	N	N	N	N	N			
157	EPN_CommentJuly31 2018	1	Exposure, RegNex, Policy	N/A	In the following sections of our public comments, the Environmental Protection Network will explain: 1) why the asbestos and HBCD problem formulations should not exclude pathways of exposure to legacy uses; 2) why the asbestos problem formulation should not exclude pathways of exposure regulated under other programs; 3) why the carbon tetrachloride problem formulation should either evaluate the conditions of use now designated as "de minimis" or provide a science-based justification for their exclusion and rationale for not seeking additional information from industry; and 4) why EPA needs to take the lead in addressing workplace risks while consulting with OSHA.	Y	N	N	N	N	Y	Y	N	N	N	Y			
158	EPN_CommentJuly31 2018	1	Exposure, Policy	N/A	1. EPA's Proposed Approach to Risk Evaluation of Exposures Related to Legacy Use Is Flawed. The exclusion of "legacy" exposures in the problem formulation documents is particularly flawed for asbestos, and very likely problematic for the cyclic aliphatic bromide cluster chemicals (HBCD) as well. While much of the current risks from asbestos occur among workers involved in asbestos abatement or removal during remodeling, demolition and disposal, there are also risks among maintenance workers with in-place asbestos and auto mechanics performing brake work. Reports published by CDC and IARC strongly suggest that these uses contribute to the widespread release of fibers into the general environment, even with adherence to OSHA and other regulatory limits.	N	N	N	N	N	Y	N	N	N	N	Y			
159	EPN_CommentJuly31 2018	1	Exposure, Human Health, Policy	N/A	It is well documented that asbestos is a carcinogenic compound. There is no safe level of exposure. The ATSDR noted that asbestos is a dangerous substance and should be avoided. Risk is dependent on frequency and duration of exposure. Breathing asbestos can cause asbestosis, lung cancer and mesothelioma. This was the finding reported in the EPA peer-reviewed report on the destruction of the World Trade Center. This report stated that the continuing release of asbestos fibers posed a serious hazard to humans unknowingly exposed to residual fibers and would continue to do so for a long period of time. Exposure risks were also addressed in an EPA 2004 pamphlet describing risks from release of asbestos fibers from brake pads. In the pamphlet, EPA stated that asbestos exposures during daily work on brakes and during the disposal of asbestos-containing products are a serious concern for the mechanics and other workers within the facility. In addition, asbestos is described in the problem formulation document as primarily a respiratory disease hazard (asbestosis, lung cancer and mesothelioma), but there is strong evidence to suggest that asbestos also poses a risk of stomach, larynx, pharynx and possibly reproductive system cancers. These risks are dismissed in the problem formulation document without explanation. They should be part of the comprehensive risk assessment. Knowing that everyone is exposed to some level of background asbestos exposure is not a reason to ignore the hazards that remain from legacy exposures such as the removal of in-place asbestos materials, and the exposure of populations who live near former mines that have produced contaminated living environments. It would be a reckless decision to ignore the long-term exposures that still occur from legacy pathways and their resultant health hazards. A recent example of asbestos exposure occurred in Manhattan when a steam pipe lined with asbestos exploded on July 19, 2018 (New York Times , July 19, 2018).	N	N	N	N	N	N	N	N	N	N	Y			

160	EPN_CommentJuly31 2018	1	Exposure, Policy, RedNex	N/A	A similar situation likely exists with regard to HBCD. While these chemicals are reportedly no longer manufactured in the U.S., they are still imported and used. There is very likely a substantial amount of legacy materials in place arising from past use in building insulation. Safer Chemicals, Healthy Families estimates that most of the 30,000 to 60,000 metric tons of HBCD used in the U.S. between 1988 and 2010 was used in building insulation and that much of it "will reach the end of its useful life in the years ahead." The potential exposure resulting from the removal of the legacy insulation through demolition, remodeling and disposal, as is the case with asbestos containing materials, may pose risks, and there are no OSHA standards to protect the workers involved in such activities. Therefore, the legacy activities involving HBCD-containing materials must be evaluated if EPA is to successfully fulfill its responsibilities to comprehensively assess and eventually manage the exposures and risks of HBCD under TSCA.	N	N	N	N	N	Y	N	N	N	N	N			
161	EPN_CommentJuly31 2018	1	RegNex	N/A	2. EPA's Proposed Approach to Risk Evaluation of Exposures Associated with Other EPA Regulatory Programs is Contrary to Plain Statutory Language and is Legally Unsound; is Scientifically and Methodologically Unsound and is Not Efficient. In each of the draft problem formulation documents for the first ten existing chemicals, EPA includes the following paragraphs (see, for example, page 13 of the 1-Bromopropane Problem Formulation): ". . . EPA also identified certain exposure pathways that are under the jurisdiction of regulatory programs and associated analytical processes carried out under other EPA-administered environmental statutes – namely, the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA), and the Resource Conservation and Recovery Act (RCRA) – and which EPA does not expect to include in the risk evaluation. As a general matter, EPA believes that certain programs under other Federal environmental laws adequately assess and effectively manage the risks for the covered exposure pathways. To use Agency resources efficiently under the TSCA program, to avoid duplicating efforts taken pursuant to other Agency programs, to maximize scientific and analytical efforts, and to meet the three-year statutory deadline, EPA is planning to exercise its discretion under TSCA 6(b)(4)(D) to focus its analytical efforts on exposures that are likely to present the greatest concern and consequently merit a risk evaluation under TSCA, by excluding, on a case-by-case basis, certain exposure pathways that fall under the jurisdiction of other EPA-administered statutes. EPA does not expect to include any such excluded pathways as further explained below in the risk evaluation. The provisions of various EPA-administered environmental statutes and their implementing regulations represent the judgment of Congress and the Administrator, respectively, as to the degree of health and environmental risk reduction that is sufficient under the various environmental statutes." Although these paragraphs are contained in all ten of the problem formulation documents, EPA offers no further definition of what it means by "under the jurisdiction" of regulatory programs or, "associated analytical processes . . .under other EPA administered statutes."	Y	N	N	N	N	N	N	N	N	N	N			
162	EPN_CommentJuly31 2018	1	RegNex	N/A	We have focused our comments on this issue in the asbestos problem formulation as an example case. All of our objections and concerns about this approach for asbestos would apply to the other nine chemicals, and depending on specifics, the use of this approach for those chemicals would likely raise additional concerns as well.	Y	N	N	N	N	N	N	N	N	N	Y			
163	EPN_CommentJuly31 2018	1	RegNex, Exposure	N/A	Comments on Exclusion of Consideration of Exposures Associated with Other EPA Regulatory Programs, with specific reference to the asbestos problem formulation: a. EPA's planned approach to exclude exposure pathways associated with other EPA statutes is contrary to plain statutory language and legally unsound. EPA cites only TSCA Sec (6)(b)(4)(D) as a basis for the decision to omit significant exposure pathways. The brief language of that provision, providing for publication of the key elements of a proposed risk assessment, offers no basis to alter the administrator's obligation under Section 6. Indeed, the treatment of risks that may also be subject to other EPA-administered statutes is expressly addressed in TSCA Sec 8(b), which provides: "(1) The Administrator shall coordinate actions taken under this chapter with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this chapter. This subsection shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws. (2) In making a determination under paragraph (1) that it is in the public interest for the Administrator to take an action under this subchapter with respect to a chemical substance or mixture rather than under another law administered in whole or in part by the Administrator, the Administrator shall consider, based on information reasonably available to the Administrator, all relevant aspects of the risk described in paragraph (1) and a comparison of the estimated costs and efficiencies of the action to be taken under this subchapter and an action to be taken under such other law to protect against such risk."	Y	N	N	N	N	N	N	N	N	N	N			
164	EPN_CommentJuly31 2018	1	RegNex	N/A	Further, the specific language of Section 6 provides, in (F) that the administrator is to "integrate and assess available information on hazards and exposures," obviously inclusive of information developed under other EPA statutes. These provisions clearly establish the role for other EPA programs: information known through other statutory programs shall be considered in the risk evaluation phase for existing chemicals under TSCA, and after completion of the risk evaluation, the administrator must follow a process to consider the potential use of other programs to address the risk under the TSCA standard. The proposed EPA approach would reverse and fundamentally alter this process.	Y	N	N	N	N	N	N	N	N	N	N			
165	EPN_CommentJuly31 2018	1	Exposure, RegNex, PESS	N/A	Further, the omission of important exposure pathways makes it impossible to make the finding required under Sec 6(b)(4)(A) which requires the administrator conduct risk evaluations "to determine whether a chemical substance presents an unreasonable risk…to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation." "Environment" is defined to include "air, water and land" and the relationship among and between these elements and with "all living things." The statute defines "conditions of use" to mean the circumstances under which the substance is "manufactured, processed, distributed in commerce, used or disposed." A risk assessment that omits exposures considered under other statutes cannot be assumed to meet this standard. Indeed, other statutory schemes generally do not operate under comparable environmental standards and requirements for consideration. They often require consideration of costs, technical feasibility or other non-risk factors. They are not designed to consider the interaction among air, land and water, but are focused instead on exposure in the specified medium. Consideration of special subpopulations is rarely required and may not even be considered under other statutory schemes. In addition, even when these other regulatory programs are implemented perfectly, they only reduce exposures down to the regulatory standard, they do not eliminate exposures.	Y	N	N	N	N	N	N	N	N	N	N			
166	EPN_CommentJuly31 2018	1	Exposure, Policy	N/A	TSCA requires specific inclusion of disposal in evaluation of the subject conditions of use; omission of disposal exposures from substances subject to RCRA may have the effect of omitting disposal entirely from the required statutory scope of consideration for the subject conditions of use.	Y	N	N	N	N	N	N	N	N	N	N			
167	EPN_CommentJuly31 2018	1	Exposure, RegNex	N/A	In the case of asbestos, the combination of determining that "legacy uses" are not conditions of use and of omitting disposal because of RCRA regulation has the effect of omitting entirely consideration of disposal, which is specifically enumerated in the statutory definition of conditions of use.	N	N	N	N	N	N	N	N	N	N	Y			
168	EPN_CommentJuly31 2018	1	RegNex	N/A	All of these inadequacies make it impossible for the administrator to rely on the work of other regulatory programs to meet the requirements for Section 6 risk evaluations. Indeed, the agency has made no attempt to show any comparability or even consistency between the TSCA risk assessment requirements and the approaches of the regulatory programs associated with these omissions.	Y	N	N	N	N	N	N	N	N	N	N			

169	EPN_CommentJuly31 2018	1	RegNex	N/A	Below are two examples from the asbestos problem formulation document that illustrate how legally insufficient the alternative programs can be for this purpose. Congress intended for TSCA to have a risk-based standard and to use this standard to evaluate high priority chemicals that had never been evaluated under other programs based only on risk. Asbestos air quality regulation dates back to 1986 and is based on an older version of the Clean Air Act (CAA), which did not require consideration of residual risk or all possible exposure pathways. Even if the existing asbestos regulation had been based on the current CAA, it would not be consistent with TSCA's sole focus on health effects. The framework for regulation of hazardous air pollutants under the current CAA is generally fundamentally different from the TSCA process. Hazardous air pollutants (HAPs) are regulated under the CAA in two stages. The first stage is based upon maximum achievable control technology (MACT) within each specific industry. Under MACT, EPA identifies the best performing technologies within an industry and sets a standard based on the performance of these technologies. The cost of achieving such emission reduction and any non-air quality health and environmental impacts and energy requirements, but not risk, are considered at this stage. The second phase of HAP control under the CAA is a "risk-based" approach in which the risk remaining after the application of MACT is assessed. Within eight years of setting the MACT standards, the CAA requires EPA to assess the remaining risks from each source category to determine whether the MACT standards protect public health with an ample margin of safety and protect against adverse environmental effects. While EPA does not have to consider the costs of any health standards imposed as a result of the risk analysis, it must consider the costs of a more stringent standard to reduce environmental risks. Furthermore, the residual risk controls only apply to major emission sources; they do not apply to small emitters considered as area sources.	N	N	N	N	N	N	N	N	N	N	Y
170	EPN_CommentJuly31 2018	1	RegNex, Policy	N/A	EPA's own discussion of the asbestos requirements under the Resource Conservation and Recovery Act illustrates clearly the gaps between the regulatory approaches to asbestos under RCRA and those required by TSCA. Indeed, the problem formulation document itself makes clear that significant amounts of the considerable quantities of disposal (>25 million pounds) from the on-going asbestos uses are subject only to certain state-level requirements. [p. 44]	N	N	N	N	N	N	N	N	N	N	Y
171	EPN_CommentJuly31 2018	1	RegNex, Policy	N/A	The amended TSCA contains new standards for assessment of chemicals, but also a host of new provisions to ensure open processes, fairness and other vital good government goals. The approaches to regulation of asbestos under other statutes generally not only have different substantive standards of review, but also different processes and procedures, especially for the risk assessment aspects of the regulatory process.	N	N	N	N	N	N	N	N	N	N	Y
172	EPN_CommentJuly31 2018	1	RegNex, Policy	N/A	EPA offers no analysis of the way in which evaluations under other statutes have met the procedural requirements of TSCA.	Y	N	N	N	N	N	N	N	N	N	N
173	EPN_CommentJuly31 2018	1	RegNex, Policy	N/A	b. EPA's planned approach to exclude important exposures associated with other EPA-statutes is also scientifically and methodologically unsound. Risk assessments that are currently available (for appropriate consideration under TSCA Sec 6(F)) are identified in the problem formulation document. Notably, the identified risk assessments under the SDWA and the CAA are from 1985 and 1986 respectively. Nothing under RCRA is identified. Obviously, these programs have not completed risk assessments reflecting changes in the science for more than 30 years. Conclusions based on any such assessments would, at a minimum, require a serious updating of most aspects of the science involved. There is no indication that EPA intends to devote the resources that would be required to update program-specific risk assessments for asbestos even for the narrow purposes of determining whether further action is warranted under such statute. EPA's other regulatory programs have limited resources and many competing priorities, including those required by specific statutory provisions and/or court orders. Congress has provided additional resources specifically for implementation of TSCA, which can compensate for the lack of resources in these other programs. In addition to the advantage TSCA affords EPA to conduct risk assessments and issue regulations covering all sources of exposure, EPA should use the potent information gathering provisions of TSCA 8(a) and 8(d) to update or supplement the risk evaluations conducted under other statutes which are so out of date today. Staff from other program offices should be involved in the assessments conducted under TSCA so they can assist the TSCA program while also updating their media-specific risk evaluations.	Y	N	N	N	N	N	N	N	N	N	N
174	EPN_CommentJuly31 2018	1	RegNex, Policy	N/A	c. EPA's planned approach to justify the exclusion of pathways regulated by other programs based on efficiency is flawed. EPA invokes efficiency as a rationale for its approach to excluding exposures under other statutes. But it is clear that nothing is preventing the agency from making use of prior work conducted under other statutes and the expertise developed throughout the agency. Further, as noted above, TSCA provides a clear path by which the administrator may, after conducting the risk assessment and making the risk findings required by TSCA, turn to all the other statutes he administers as part of crafting a risk management approach for existing chemicals under TSCA. This extreme, legally and scientifically unsound refusal to consider significant exposures clearly resulting from current conditions of use is not warranted on efficiency grounds.	Y	N	N	N	N	N	N	N	N	N	N
175	EPN_CommentJuly31 2018	1	Policy	2.2.2.1	3. EPA's Prosposed Approach to Risk Evaluation of Pathways Deemed De minimis is Flawed. In the carbon tetrachloride problem formulation, EPA asserts without justification that it will exclude multiple uses of the chemical (cleaning and degreasing solvents, adhesives and sealants, paints and coatings) because they pose only de minimis risks. This was the only problem formulation that excluded uses because they were deemed de minimis. While the final chemical risk evaluation rule mentions that de minimis uses could be excluded from consideration, no criteria were provided for determining a use that poses de minimis risks for a chronic toxicant. Since carbon tetrachloride is a carcinogen, EPA must document in the problem formulation the carcinogenic risk level used to designate a pathway as posing de minimis risk. In addition, combined low level exposures resulting from multiple uses and sources of a chemical can result in unreasonable risks to particular subpopulations, so EPA must document that co-occurring de minimis pathways were appropriately evaluated in combination and still found to be below the carcinogenic level of concern if people can experience more than one of these pathways at any given time. Further, the carbon tetrachloride problem formulation should justify why EPA is not using its authority to request new testing by industry to better evaluate these de minimis pathways. The new testing provision of the Chemical Safety Act is clear that the administrator must not interpret the lack of exposure information as a lack of exposure or exposure potential and must seek new information to resolve this issue.	N	N	N	N	N	N	Y	N	N	N	N
176	EPN_CommentJuly31 2018	1	RegNex, Exposure	N/A	4. EPA's Potential Approach to Rely on OSHA to Regulate Worker Exposure is Flawed. In addition to the inadequacy of EPA's proposed exclusion of exposures that are "already regulated" by EPA (by statutes other than TSCA, such as the CAA), as discussed above in these comments, this exclusion also reveals a potentially very serious flaw in EPA's methods if the agency intends to apply the same approach to workplace exposures. The Chemical Safety Act requires EPA to consult with OSHA "prior to adopting any prohibition or other restriction relating to a chemical substance with respect to which the Administrator has made a determination to address workplace exposures." So far, the agency has been silent regarding how it intends to address workplace risks, but the strategy of having EPA "punt" its responsibilities regarding workers by transferring them to OSHA is being heavily advocated by industry groups, and it must not remain unchallenged. Any wholesale "referral" to OSHA for potential regulation would in effect leave the workers unprotected, because it is well known that OSHA is unable to promulgate occupational health standards in a timely fashion, if at all.	Y	N	N	N	N	N	N	N	N	N	N

177	EPN_CommentJuly31 2018	1	RegNex, Exposure	N/A	To better understand this concern, it is important to note that all ten chemicals slated for analysis at this stage of the TSCA mandates, and eventually slated for potential regulation, have their highest exposures and pose their most serious risks to workers who manufacture, process, transport, dispose of or otherwise handle these chemicals. This is no surprise: workers are nearly always the first and most seriously exposed populations, experiencing the highest risks. In addition, four of the chemicals [1-BP, HBCD, NMP, and PV29] are not regulated at all by OSHA, and the remaining six are currently regulated by OSHA standards that are scientifically obsolete, based on studies more than a half century old. Because of OSHA's inability to regulate in a timely manner, referral of the responsibility to regulate these chemicals would condemn workers to significant risks for a long time, or even indefinitely.Table 1 shows the contrast between current OSHA standards for the ten chemicals with more modern standards (Cal-OSHA) or recommendations (NIOSH and ACGIH). It is evident that current OSHA protections are highly inadequate and TSCA regulation will be necessary. [Table 1 illustrates differences between OSHA PELs, Cal-OSHA PELs, NIOSH RELs, and ACGIH TLVs. The values for asbestos were the same across all standards/guidelines, and the values for OSHA and CAL-OSHA were the same for methylene chloride (25 ppm). Values for the other standards/guidelines were less than OSHA for all other chemicals.]	Y	N	N	N	N	N	Y	N	N	N	N
178	EPN_CommentJuly31 2018	1	RegNex, Exposure	N/A	While it is commendable that the agency recognizes the workplace hazards posed by these chemicals and intends to evaluate the risks at this stage, it is crucial that EPA state explicitly that it will take steps to make sure that workplace risks are regulated in a timely fashion under TSCA, even as OSHA, NIOSH and other agencies are consulted in the process of doing so, as TSCA allows.	Y	N	N	N	N	N	N	N	N	N	N
179	Healey_CommentAugust72018	1	General	N/A	The Attorneys General of Massachusetts, California, Hawaii, Maine, Maryland, New Jersey, New York, Oregon, Vermont, Washington, the District of Columbia, and Rhode Island appreciate this opportunity to comment on the U.S. Environmental Protection Agency's ("EPA") problem formulations of the risk evaluations for the ten chemical substances (the "Initial Ten TSCA Chemicals") that are the subject of EPA's initial chemical risk evaluations required under the Frank R. Lautenberg Chemical Safety for the 21st Century Act (the "Lautenberg Act"), amending the Toxic Substances Control Act (TSCA). In its notice dated June 11, 2018, EPA requested comments on the problem formulation documents for the Initial Ten TSCA Chemicals (the "Problem Formulations") to assist the agency in developing its draft risk evaluations for these chemical substances. The Attorneys General submit the following comments for EPA's consideration as EPA proceeds with its risk evaluations of the Initial Ten TSCA Chemicals.	Y	N	N	N	N	N	N	N	N	N	N
180	Healey_CommentAugust72018	1	General	N/A	The undersigned Attorneys General support the goal that motivated the Lautenberg Act amendments to TSCA, signed into law on June 22, 2016: the goal of reforming TSCA to remove obstacles that had prevented EPA from playing a more robust role in protecting public health and the environment from toxic chemicals. Unfortunately, the Problem Formulations are antithetical to that purpose. EPA takes the position that TSCA authorizes the agency to consider in its risk evaluation a mere subset of the uses for which the chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed. That interpretation would result in EPA's risk evaluations being woefully incomplete by ignoring significant exposure pathways for the chemical substances. This unlawfully restrictive application of TSCA ignores that Congress intended for EPA to assess a chemical in its entirety, based on all identifiable conditions of use, including ongoing and legacy uses, like the ubiquitous continued use of notoriously hazardous asbestos, in its risk evaluations. For this reason, the Problem Formulations would produce deeply flawed risk evaluations that would make it impossible for EPA to fulfill its statutory mandate under Section 6 of TSCA of establishing requirements for the Initial Ten TSCA Chemicals to ensure that none of the chemical substances presents "an unreasonable risk of injury to health or the environment." We thus urge EPA to issue revised Scopes of the Risk Evaluation, which the Problem Formulations are meant to refine, for each of the Initial Ten TSCA Chemicals to address the agency's fatally flawed approach to identifying the conditions of use as that term is understood under TSCA and to ensure that the data EPA considers in the process satisfies TSCA's "best available science" standards. Given the well-documented hazards of many of the Initial Ten TSCA Chemicals, we fully expect that after conducting appropriate risk evaluations, EPA will impose new protective restrictions, and in some cases bans, for the chemical substances in this group.	Y	N	N	N	N	N	N	N	N	N	N
181	Healey_CommentAugust72018	1	General	N/A	These comments proceed as follows. In Part I, we describe TSCA's requirements for the risk evaluations. In Part II, we provide a summary of our states' interests with regard to the risk evaluations. In Part III, we offer analysis supporting our call for EPA to reconsider its approach to its conditions of use characterizations and to ensure that data consistent with TSCA's requirements are considered in the risk evaluation process. Finally, we suggest an appropriate risk evaluation path forward that will satisfy Congress's mandate under TSCA that EPA act to eliminate unreasonable risks of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to potentially exposed or susceptible subpopulations.	Y	N	N	N	N	N	N	N	N	N	N
182	Healey_CommentAugust72018	1	General/Exposure	N/A	Under TSCA, as amended, EPA is required to prioritize chemical substances for regulatory review and then assess the risks posed by the chemicals identified as priorities. Risk is a function of hazard and exposure, and to evaluate the risks posed by a chemical as TSCA requires it is necessary to consider the full range of exposures. However, in the Problem Formulations EPA has, without basis in law or fact, eliminated from its risk evaluation process many significant sources of chronic exposure to these toxic chemical substances. Section 6 of TSCA requires EPA systematically to prioritize for risk evaluation, and to evaluate the potential risks presented by, the manufacture, processing, distribution in commerce, use, or disposal of chemical substances or mixtures. Within 180 days of enactment of the 2016 TSCA amendments, that is by December 19, 2016, EPA was required to begin risk evaluations on ten chemical substances drawn from the agency's TSCA Work Plan for Chemical Assessments: 2014 Update (the "2014 TSCA Work Plan Update") and to publish the list of such chemical substances during the 180-day period. On December 19, 2016, EPA designated the Initial Ten TSCA Chemicals for risk evaluation: Asbestos, 1-Bromopropane, 1,4-Dioxane, Carbon Tetrachloride, Cyclic Aliphatic Bromide Cluster (also known as HBCD), Methylene Chloride, N-Methylpyrrolidone (NMP), Pigment Violet 29, Tetrachloroethylene (also known as Perchloroethylene), and Trichloroethylene (TCE).	Y	N	N	N	N	N	N	N	N	N	N
183	Healey_CommentAugust72018	1	General	N/A	Under TSCA, Section 6(b)(4)(A), EPA is required to conduct a risk evaluation for each of the Initial Ten TSCA Chemicals, and for chemicals later designated as "high-priority," to determine whether the ". . . chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of cost or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." And under TSCA, Section 6(b)(4)(D), EPA was required to publish the scope of the risk evaluation to be conducted for each of the Initial Ten TSCA Chemicals within six months after the initiation of the risk evaluation. On July 7, 2017, EPA published its Notice of Availability for the Scopes of the Risk Evaluations To Be Conducted for the First Ten Chemical Substances Under the Toxic Substances Control Act. Under TSCA, those scopes must include the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider in his or her analysis. Thereafter, EPA published the subject Problem Formulations in the Federal Register on June 11, 2018,16 with the Problem Formulations being said to function to refine the earlier-published scope documents.	Y	N	N	N	N	N	N	N	N	N	N

184	Healey_CommentAugust72018	1	General	N/A	Our states have a significant interest in ensuring that the risk evaluations for the Initial Ten TSCA Chemicals are conducted in accordance with TSCA. The Initial Ten TSCA Chemicals were drawn from the agency's 2014 TSCA Work Plan Update, as required by TSCA, and were selected based on their hazard and potential exposure, as well as other factors such as persistence and bioaccumulation. For example, asbestos is a known carcinogen, with acute and chronic toxicity associated with inhalation exposures; tetrachloroethylene (also known as perchloroethylene or perc) is a probable human carcinogen with high reported releases to the environment; and n-methylpyrrolidone (NMP) has high reported releases to the environment and is associated with reproductive toxicity. The potential for substantial harm to public health and the environment associated with the Initial Ten TSCA Chemicals resulted in their being chosen as the first candidates for risk evaluation. Thus, the consequences for our states' residents of a federal failure to identify those risks and to regulate accordingly may be dire, with the potential for even greater risk to susceptible subpopulations, where the failure to perform a full analysis may have the most severe adverse impact. As evidenced by the following overview of actions by many of the participating states and the District of Columbia, the unreasonable risks to human health and the environment that the Initial Ten TSCA Chemicals pose justifies governmental response. In fact, it is just such health- and environment-protective regulation at the federal level that informed the 2016 amendments to TSCA. Additionally, the data listed below that demonstrates the prevalence of the Initial Ten TSCA Chemicals in our states further confirms the states' significant interest in ensuring that EPA implements TSCA as it was revised by the Lautenberg Act: to eliminate "unreasonable risk of injury to health or the environment" from the "intended, known, or reasonably foreseen" manufacturing, processing, distribution in commerce, use, or disposal of chemicals.	Y	N	N	Y	N	N	N	N	Y	N	Y
185	Healey_CommentAugust72018	1	General	N/A	Massachusetts: Under the Massachusetts Toxics Use Reduction Act, G.L. c. 21I ("TURA"), large-quantity chemical users in the Commonwealth are required to report annually on their use of toxic chemicals and conduct toxics use reduction planning every two years. Each of the Initial Ten TSCA Chemicals, with the exception of Cyclic Aliphatic Bromide Cluster, also known as HBCD, and Pigment Violet 29, are on the TURA chemicals list and are subject to TURA's requirements.23 Moreover, the TURA program may designate "Higher" or "Lower Hazard Substances" within the larger TURA list of Toxic or Hazardous Substances. If a chemical is designated as a Higher Hazard Substance (HHS) under TURA, the thresholds for reporting for those chemicals are lowered. To date, the TURA program has designated 14 chemicals or chemical categories as HHS. Four of the Initial Ten TSCA Chemicals are designated as HHS under TURA: trichloroethylene, perchloroethylene, 1-bromopropane, and methylene chloride.25 Footnotes 23 That HBCD and Pigment Violet 29 are not listed does not represent any judgment of the toxicity of these chemicals. It simply means that they have not been taken up for consideration and possible addition to the TURA list and they may later be added to the TURA list. 25 That six of the Initial Ten TSCA Chemicals are not designated as HHS in Massachusetts does not mean that the TURA program considers them to be less toxic than others. Rather, it means that those chemicals have not yet been addressed under this regulatory process.	Y	N	N	N	N	N	N	N	N	N	N
186	Healey_CommentAugust72018	1	General	N/A	In Massachusetts, the Toxics Use Reduction Institute ("TURI"), created under TURA, Section 6, and the Massachusetts Office of Technical Assistance and Technology ("OTA"), its partner agency, work with Massachusetts businesses to reduce the use of toxic chemicals in the state. TURI and OTA are engaged in on-going work to help Massachusetts businesses and communities reduce their use of toxic solvents including trichloroethylene, perchloroethylene, methylene chloride, 1-bromopropane, and n-methylpyrrolidone, as well as helping businesses adopt safer alternatives to toxic flame retardants, among other efforts. This work to assist Massachusetts businesses and communities complements other regulatory activities within the Commonwealth to protect workers, communities and the environment from these and other toxic chemicals.	N	Y	N	Y	N	Y	N	Y	Y	Y	N
187	Healey_CommentAugust72018	1	General	N/A	Massachusetts also comprehensively regulates asbestos through a set of overlapping state and delegated federal programs involving multiple state agencies. From 2011–2015, the U.S. Centers for Disease Control and Prevention (CDC) reports there were 441 new cases of mesothelioma in Massachusetts, resulting in 366 deaths. Asbestos exposure is the known cause of mesothelioma. •The Massachusetts Department of Environmental Protection ("MassDEP") is authorized by the Massachusetts Clean Air Act, M.G.L. c. 111, §§ 142A-O, and the federal Clean Air Act, 42 U.S.C. § 7401, et seq., to prevent air pollution by regulating asbestos handling, transport, and disposal. • MassDEP requires notice and remediation of releases of asbestos to the environment as a hazardous material under the state's "superfund" law, M.G.L. c. 21E. • MassDEP also regulates the disposal of asbestos under the Massachusetts Solid Waste Management Act, M.G.L. c. 111, § 150A. • The Massachusetts Department of Labor Standards ("DLS") ensures worker safety in Massachusetts by licensing asbestos-related work and requiring the use of proper work practices and safety equipment pursuant to M.G.L. c. 149. • DLS is also delegated authority under the Asbestos Hazard Emergency Response Act, 15 U.S.C. § 2641, et seq., to regulate asbestos in schools for the safety of the school community. • The Massachusetts Office of the Attorney General is empowered to initiate litigation to enforce these state statutes and to seek court orders for compliance and civil penalties. The Attorney General also conducts other work to encourage the safe use and public awareness of asbestos, such as leading a multi-party stakeholder effort to create a comprehensive online public database of asbestos information about Massachusetts schools in response to a report by the Office of Senator Edward J. Markey identifying a lack of this information nationally.	N	N	N	N	N	N	N	N	N	N	Y
188	Healey_CommentAugust72018	1	Other, Policy	N/A	California: Because of the significant harm to human health and the environment that the Initial Ten TSCA Chemicals pose, California has implemented regulatory measures including, but not limited to: prohibiting the sale, supply, and manufacturing for use of specified consumer product categories that contain any of the following compounds: TCE, PCE, or methylene chloride; regulating exposure to asbestos in construction work, general industry, shipyards and prohibiting sale of brake pads with asbestiform fibers above .1% weight.	N	N	N	Y	N	N	N	Y	N	Y	Y
189	Healey_CommentAugust72018	1	Other, Policy	N/A	California has proposed regulation of methylene chloride in varnish and paint strippers under its Safer Consumer Products regulations (Cal. Code Regs., tit. 22, § 69501, et seq.).	N	N	N	N	N	N	N	Y	N	N	N
190	Healey_CommentAugust72018	1	Other, Policy	N/A	With the exception of HBCD and Pigment Violet 29, each of the Initial Ten TSCA Chemicals is listed as either a carcinogen and/or reproductive toxin under California's Safe Drinking Water and Toxic Enforcement Act of 1986 known as "Proposition 65."	N	Y	Y	Y	N	N	Y	Y	Y	Y	Y

191	Healey_CommentAugust72018		1	Other, Policy	N/A	The adverse impacts to California these substances cause are further demonstrated by the following: • From 2011–2015, the CDC reports there were 1,716 new cases of mesothelioma in California, resulting in 1,318 deaths. Asbestos exposure is the known cause of mesothelioma. • There have been at least two deaths in California caused by exposure to paint strippers containing methylene chloride since 2012. • There are 37 sites in California with TCE contamination that have been or are on the National Priorities List (NPL) under the Comprehensive Environment Response, Compensation and Liability Act (CERCLA), 29 with PCE contamination, 6 with asbestos contamination, 10 with 1,4-dioxane contamination, 36 with methylene chloride contamination, and 25 with carbon tetrachloride contamination. • In 2016, the most current Toxic Release Inventory (TRI) reporting year, a combined total of 2,124,369 pounds of 1,4-dioxane, asbestos, carbon tetrachloride, NMP, PCE and TCE was reported as having been disposed of or released in California.	N	N	Y	Y	N	N	Y	N	Y	Y	Y
192	Healey_CommentAugust72018		1	Other, Policy	N/A	Maine: Under the Maine Priority Toxic Chemical Use Reduction law, 38 Maine Revised Statutes ("M.R.S.") §§ 2331-2330, and corresponding rule, 06-096 Code of Maine Rules ("CMR") ch. 82, commercial and industrial facilities using more than 1,000 pounds/year of a priority toxic chemical listed in Maine's rule, 06-096 CMR ch. 81, must report their usage of the chemical and must develop a pollution prevention plan, which must be updated every two years. Maine has identified five chemicals as priority toxic chemicals under this law, two of which are on the list of Initial Ten TSCA Chemicals—perchloroethylene and trichloroethylene.	N	N	N	Y	N	N	N	N	N	Y	N
193	Healey_CommentAugust72018		1	Other, Policy	N/A	Maine regulates several of the chemicals on the list of Initial Ten TSCA Chemicals as hazardous matter and hazardous substances. In addition, Maine regulates control technology for dry cleaners using perchloroethylene.	Y	N	N	Y	N	N	N	N	N	N	N
194	Healey_CommentAugust72018		1	Other, Policy	N/A	Maine also comprehensively regulates asbestos abatement activities to ensure safe working conditions pursuant to its asbestos law, 38 M.R.S. §§ 1271-1284, and its corresponding rule, 06-096 CMR ch. 425, and the disposal and transportation of asbestos under its Solid Waste Management Rules, 06-096 CMR ch. 401 (disposal); 06-096 CMR ch. 411 (transportation). Additionally, in Maine, all sellers of residential real property are required to disclose the presence of asbestos or the prior removal of asbestos to potential buyers.39 From 2011–2015, the CDC reports there were 128 new cases of mesothelioma in Maine, resulting in 107 deaths. Moreover, the Maine Department of Environmental Protection has been delegated by the U.S. Environmental Protection Agency to conduct periodic Asbestos Hazard Emergency Response Act (AHERA) compliance inspections in Maine's non-profit school systems.	N	N	N	N	N	N	N	N	N	N	Y
195	Healey_CommentAugust72018		1	Other, Policy	N/A	Maryland: Maryland regulates the manufacture, sale, use, and disposal of chemicals—including some of the substances to be addressed in EPA's initial risk evaluations—in a variety of ways. For instance, businesses engaged in the removal or encapsulation of asbestos may do so only pursuant to a license issued by the Maryland Department of the Environment—which, in turn, has prescribed strict procedures governing such activities. From 2011–2015, the CDC reports there were 258 new cases of mesothelioma in Maryland, resulting in 207 deaths.	Y	N	N	N	N	N	N	N	N	N	Y
196	Healey_CommentAugust72018		1	Other, Policy	N/A	More broadly, the Department regulates the disposal of hazardous waste, including substances included in EPA's Initial Ten TSCA Chemicals. Maryland Department of the Environment regulations generally prohibit the sale, supply, offer for sale, or manufacture for use in the state of adhesives, cleaners, and other products containing methylene chloride, perchloroethylene, or trichloroethylene. Additionally, the Maryland Secretary of Health may declare a substance to be "hazardous material" and establish labeling requirements or, where appropriate, ban the substance. The Secretary has exercised this authority by incorporating by reference Parts 1500 and 1505 of Title 16 of the Code of Federal Regulations (implementing the Federal Hazardous Substances Act). The Secretary is authorized to inspect facilities where hazardous material may be manufactured, processed, packaged, or stored, as well as vehicles used to transport or hold such material.	Y	N	N	Y	N	N	N	Y	N	Y	N
197	Healey_CommentAugust72018		1	Other, Policy	N/A	New York: New York regulates the manufacture, sale, use and disposal of chemicals, including some at issue in the Problem Formulations, in a variety of ways. For example, New York has a de facto ban on the use of 1-bromopropane, also known as n-propyl bromide, in dry cleaning. New York will not issue an Air Facility Registration to any facility proposing to use that chemical as an alternative dry cleaning solvent as it is not an approved alternative solvent.	Y	Y	N	N	N	N	N	N	N	N	N
198	Healey_CommentAugust72018		1	Other, Policy	N/A	New York has spent millions of dollars cleaning up tetrachloroethylene (perc) and trichloroethylene at hazardous waste sites.	N	N	N	Y	N	N	N	N	N	Y	N
199	Healey_CommentAugust72018		1	Other, Policy	N/A	To help remove 1,4-dioxane from drinking water on Long Island, New York has conditionally approved a new treatment technology.	N	N	Y	N	N	N	N	N	N	N	N
200	Healey_CommentAugust72018		1	Other, Policy	N/A	As regards asbestos, New York has a number of regulatory programs in place: the Department of Health certifies and trains employees who perform asbestos abatement; the Department of Labor regulates asbestos abatement and removal projects; and the Department of Environmental Conservation regulates the transportation and disposal of asbestos waste.	N	N	N	N	N	N	N	N	N	N	Y
201	Healey_CommentAugust72018		1	Other, Policy	N/A	Oregon: Oregon has adopted, and is considering, several state-specific statutes and regulations to manage the impacts of toxic and hazardous pollutants that encompass the majority of the Initial Ten TSCA Chemicals. These programs include: • Asbestos emissions, disposal, licensing and certification requirements. From 2011–2015, the CDC reports there were 245 new cases of mesothelioma in Oregon, resulting in 223 deaths. • Air toxics permits and benchmarks for industrial facilities. In addition, Oregon is currently in the process of developing new rules on industrial air emissions that would regulate emissions based on health risks to neighboring communities. The proposed rules will regulate emissions of hundreds of chemicals, including several of the Initial Ten TSCA Chemicals: asbestos, 1-bromopropane, carbon tetrachloride, 1,4 dioxane, tetrachloroethylene, and trichloroethylene. Oregon is relying on federal guidance and expertise to help define potential health risks for communities that are exposed to these emissions and to ensure that communities are protected from cumulative risks from other potential exposure pathways. • Toxics Use and Hazardous Waste Reduction planning requirements, which apply to large and small quantity generators of hazardous waste and Toxic Release Inventory reporters. • State cleanup and remedial actions for hazardous substances, and separate rules for dry cleaning facilities with perchloroethylene (tetrachloroethylene). In addition, legacy contamination from industrial sites is still a potential source of exposure to several of the Initial Ten TSCA Chemicals. The Oregon Health Authority's Environmental Health Assessment Program evaluates potential public health risks from contaminated sites across our state. In the last year alone, the program has been asked to evaluate public health risks from sites where environmental monitoring projects detected at least one of the Initial Ten TSCA Chemicals, including 1,4 dioxane, carbon tetrachloride, methylene chloride, tetrachloroethylene, and/or trichloroethylene. • Oregon adopted the Toxic Free Kids Act in 2015, requiring manufacturers of children's products to report the presence of specific chemicals of concern in products sold in Oregon. Several of the Initial Ten TSCA Chemicals are being reported in that program, including 1,4 dioxane, methylene chloride, tetrachloroethylene, and hexabromocyclododecane. Oregon relies on information from federal agencies to evaluate potential health risks of chemicals of concern for children, to identify new chemicals of concern to add to the reporting list, and to help address cumulative risks from these chemicals through other routes of exposure.	Y	Y	Y	Y	N	Y	Y	Y	N	Y	Y
202	Healey_CommentAugust72018		1	Other, Policy	N/A	Across all of these programs, Oregon has compiled data documenting the presence of the majority of the Initial Ten TSCA Chemicals in various environmental media. EPA must consider the full scope of impacts from these chemicals in states like Oregon in determining the scope of TSCA risk evaluations for the Initial Ten TSCA Chemicals.	Y	N	N	N	N	N	N	N	N	N	N

203	Healey_CommentAugust72018	1	Other, Policy	N/A	Washington: The Washington State Waste Reduction Act ("WRA") was enacted "[i]n the interest of protecting the public health, safety, and the environment[.]"Under the WRA, any person generating over 2,640 pounds of hazardous waste annually is required to "prepare a plan for the voluntary reduction of the use of hazardous substances and the generation of hazardous wastes." The Revised Code of Washington 70.95C.020 provides that both dangerous waste and extremely hazardous waste "shall specifically include those wastes designated as dangerous by rules adopted pursuant to chapter 70.105 RCW." Accordingly, pursuant to RCW 70.105, the Washington State Department of Ecology ("Ecology") has designated five of the Initial Ten TSCA Chemicals as dangerous wastes subject to voluntary reduction plans.	Y	N	N	N	N	N	N	N	N	N	N
204	Healey_CommentAugust72018	1	Other, Policy	N/A	Within Ecology, the WRA establishes an office of waste reduction (also referred to as Ecology). Ecology's duties, in part, include encouraging the reduction of hazardous waste use, coordinating with all state agency programs to provide technical assistance, and coordinating public education programs on waste reduction. Additionally, Ecology provides technical assistance in preparing plans pursuant to WRA in an effort to reduce the use of such dangerous wastes.	Y	N	N	N	N	N	N	N	N	N	N
205	Healey_CommentAugust72018	1	Other, Policy	N/A	In the context of hazardous waste and toxics reduction, Washington State has additional statutes that authorize Ecology to regulate asbestos and many Initial Ten TSCA Chemicals due to their associated harms to public health and the environment. For example, Washington's Better Brakes Law mandates a phase out of asbestos in brake friction material that is sold, or offered for sale, in Washington State. From 2011–2015, the CDC reports there were 463 new cases of mesothelioma in Washington State, resulting in 394 deaths.	N	N	N	N	N	N	N	N	N	N	Y
206	Healey_CommentAugust72018	1	Other, Policy	N/A	In addition, under Washington's Children's Safe Products Act, manufacturers whose products contain certain chemicals, like N-Methylpyrrolidone, methylene chloride, tetrachloroethylene, and HBCD, must annually report to Ecology.	N	N	N	Y	N	Y	N	Y	Y	N	N
207	Healey_CommentAugust72018	1	Other, Policy	N/A	With respect to children's products containing HBCD, a flame retardant, Ecology is required to evaluate "potential impacts on human health and the environment resulting from . . . [chemical] exposure" when developing policies and recommendations.	N	N	N	N	N	Y	N	N	N	N	N
208	Healey_CommentAugust72018	1	Other, Policy	N/A	Ecology collaborates with many state agencies, such as the Washington State Department of Health, and works with industries and environmental stakeholders, to identify chemicals that pose the highest risks to human health and the environment. Thereafter, Ecology develops and enforces policies, toxic chemical regulations, and plans to reduce or eliminate the use of toxic chemicals.	Y	N	N	N	N	N	N	N	N	N	N
209	Healey_CommentAugust72018	1	Other, Policy	N/A	Distric of Columbia: The District of Columbia's Hazardous Waste Management Act includes provisions for toxic chemical source reporting and reduction. Businesses identified by the Standard Industrial Classification (SIC) as the largest generators or within the top 25% of all hazardous waste generators within the District, or that release a toxic chemical subject to regulation are required to file an annual Toxic Release Inventory (TRI) Form R for each TRI-listed chemical it manufactures, processes or otherwise uses in quantities above the threshold reporting quantity. In addition, reporting facilities must prepare and submit a toxic chemical source reduction plan which must be updated every four years. TRI-listed chemicals include the following toxic substances included in the Initial Ten TSCA Chemicals: trichloroethylene, 1-bromopropane and n-methylpyrrolidone.	N	Y	N	N	N	N	N	N	Y	Y	N
210	Healey_CommentAugust72018	1	Other, Policy	N/A	The District also regulates the removal and abatement of asbestos through its own licensing and permitting requirements to ensure the safe removal and disposal of asbestos-containing material and the safety of asbestos abatement workers and the surrounding community.	N	N	N	N	N	N	N	N	N	N	Y
211	Healey_CommentAugust72018	1	General	N/A	Under Section 6(b)(4)(A) of TSCA, EPA conducts risk evaluations to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . under the conditions of use." And the term "conditions of use" is defined as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."	Y	N	N	N	N	N	N	N	N	N	N
212	Healey_CommentAugust72018	1	Exposure, PESS	N/A	So, under TSCA, EPA must conduct risk evaluations to determine whether a "chemical substance" presents an unreasonable risk under the circumstances under which that substance is "intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." The plain language of the statue requires EPA to evaluate the risks of each chemical substance identified for evaluation under all circumstances for which exposures can be anticipated, including the so-called "legacy" uses, which clearly are circumstances under which these chemicals are "known . . . to be . . . used or disposed of." Without basis in law or fact, the risk evaluation scheme reflected in the Problem Formulations fails to evaluate the risks for each chemical under all circumstances for which exposures can be anticipated and by failing to do so frustrates TSCA's purposes by ignoring exposures and underestimating risks posed by the chemical substances. For example, where the hazard posed by a chemical may relate to multiple exposure pathways, ignoring one of these pathways may result in underestimating the total, cumulative risk posed by the chemical. Such underestimation may adversely impact determinations of risk to certain populations, including those who are particularly exposed or sensitive to the chemical's adverse effects. Therefore, any risk evaluations conducted under the risk evaluation scheme reflected in the Problem Formulations cannot satisfy EPA's mandate under TSCA.	Y	N	N	N	N	N	N	N	N	N	N
213	Healey_CommentAugust72018	1	Exposure	2.2	1. EPA is Ignoring Highly Risky "Legacy Uses," Putting Public Health and the Environment in Grave Peril. In the Problem Formulations, EPA has eliminated from its analysis many of the most important sources of chronic exposure to these toxic chemicals by defining away these exposure pathways through the agency's unjustified narrowing of the conditions of use it will consider. Most significant, perhaps, is EPA's irrational decision to eliminate so-called "legacy" uses from its evaluations. This willful ignorance is both unlawful and patently dangerous based on the hazards both to people and the environment presented by unaccounted-for exposures to any of the Initial Ten TSCA Chemicals.	Y	N	N	N	N	N	N	N	N	N	N
214	Healey_CommentAugust72018	1	Exposure, PESS	2.2	The most glaring and egregious example of this dereliction of EPA's statutory obligations comes in the Problem Formulation for asbestos. Asbestos is a known carcinogen and there is no safe level of exposure to this highly toxic material ubiquitous in our built environment. The potential for harm posed by asbestos is universally recognized and addressing its risks was a priority in reforming TSCA: "Asbestos, for example, is one of the most harmful chemicals known to humankind, and it takes 15,000 lives a year. It is linked to a deadly form of lung cancer called mesothelioma. People can breathe in these fibers deep into their lungs where they cause serious damage. We have addressed asbestos in this bill. We didn't ban it on this bill, which I support . . . but we have made asbestos a priority in this bill." EPA's failure to consider so-called "legacy" uses of asbestos (e.g., asbestos currently in place in buildings and on pipes and equipment) in its risk evaluation process, and the agency's failures otherwise to identify properly the conditions of use for asbestos, means EPA will not consider the risks from, among others, aging asbestos-containing tiles, adhesives, and piping in millions of homes, commercial buildings, and in underground infrastructure nationwide. 81 By failing to identify and assess exposures from the full range of known and likely uses, EPA is failing to characterize the full range of risks posed by asbestos and thus cannot possibly satisfy its mandate under TSCA to eliminate unreasonable risks of injury to health or the environment, without consideration of costs or other non-risk factors, including unreasonable risks to a potentially exposed or susceptible subpopulation. Footnote 81 Legacy uses of asbestos excluded from the scope of the risk evaluation include: asbestos arc chutes; asbestos packings; asbestos pipeline wrap; asbestos protective clothing; asbestos separators in fuel cells and batteries; asbestos-cement flat sheet: asbestos-cement pipe and fittings; asbestos-cement shingles; asbestos-reinforced plastics; automatic transmission friction components; beater-add gaskets; clutch facings; corrugated asbestos-cement sheet; extruded sealant tape; filler for acetylene cylinders; high-grade electrical paper; millboard; missile liner; roofing felt; and vinyl-asbestos floor tile. See Scope of the Risk Evaluation for Asbestos, Jun. 2017, pp. 24-25, available at: https://www.epa.gov/sites/production/files/2017-06/documents/asbestos_scope_06-22-17.pdf.	N	N	N	N	N	N	N	N	N	N	Y

215	Healey_CommentAugust72018	1	Exposure, PESS	2.2	The vast majority of the asbestos currently in place in the U.S. is in the form of "legacy" materials. The relatively small amounts of new asbestos being introduced into the United States, as documented by EPA in the asbestos Problem Formulation pales in comparison to the amount of asbestos currently in place in buildings, vehicles, underground, and elsewhere. While only approximately 300 metric tons, or 661,387 pounds, of asbestos was imported into the U.S. in 2017, an amount of approximately 11,598 metric tons, or 25,568,292 pounds, of asbestos containing materials has been documented as having been disposed of as solid waste or otherwise released in the U.S. in 2015. These so-called "legacy" use materials continue to present very significant exposure risks, both in the asbestos abatement process and as a result of environmental releases from the disturbance of "legacy" materials that are not subject to the abatement process. For example, the cutting and beveling of asbestos cement pipe leads to extremely high airborne concentrations of asbestos fibers putting workers at risk.	N	N	N	N	N	N	N	N	N	N	Y
216	Healey_CommentAugust72018	1	Exposure	2.2	EPA does not even attempt to provide a rationale for ignoring exposures related to the current widespread and most common uses of asbestos by excluding so-called "legacy" uses from its risk evaluations under Section 6 of TSCA. Rather than providing either legal or data-based justifications for its decision, the agency merely states: "EPA interprets the mandates under section 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on current and prospective uses for which manufacture, processing, or distribution in commerce is intended, known or reasonably foreseen, rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of "conditions of use" in that context (TSCA section 6(b)(4)(B)). In other words, EPA interprets the risk evaluation process of section 6 to focus on the continuing flow of chemical substances from manufacture, processing and distribution in commerce into the use and disposal stages of their life cycle. Consistent with this rationale, EPA has excluded certain uses from the scope of the risk evaluation, as identified below." [p. 20]	N	N	N	N	N	N	N	N	N	N	Y
217	Healey_CommentAugust72018	1	Exposure	2.2	Another "legacy" use not included in EPA's Scope of the Risk Evaluation for Asbestos is the use of Libby Amphibole asbestos (which EPA describes as "a mixture of several mineral fibers such as winchite, richterite, and tremolite found in vermiculite ore near Libby, Montana). This notwithstanding that EPA readily admits Libby Amphibole has the potential for human exposure: "Although vermiculite contaminated with the Libby Amphibole remains in buildings as an insulating material and therefore presents the potential for human exposure, vermiculite containing the Libby Amphibole is no longer manufactured or processed for use in the United States and therefor is not considered a condition of asbestos use for the purpose of risk evaluation under TSCA." Here, EPA is arbitrarily and capriciously limiting the uses that qualify as conditions of use to future applications, even while confirming the potential for human exposure as well as the risks to human health presented by such exposures.	N	N	N	N	N	N	N	N	N	N	Y
218	Healey_CommentAugust72018	1	Other, Exposure	N/A	Moreover, EPA is taking inconsistent and irreconcilable positions with respect to how it views conditions-of-use determinations. On February 17, 2017, the current administration's EPA announced the availability of EPA's response to a petition EPA received in November 2016 under Section 21 of TSCA from a group of organizations, including Fluoride Action Network, Food & Water Watch, and the Organic Consumers Association, asking EPA to exercise its TSCA Section 6 authority to ban the purposeful fluoridation of U.S. water supplies. In its denial of the petition, EPA interpreted TSCA's requirements for determining "conditions of use" for risk evaluations under Section 6 of TSCA as appropriately very broad consistent with the intent of Congress in reforming TSCA. In its finding issued less than eighteen months ago, EPA announced: "Unless EPA establishes an exemption under TSCA section 6(g) (whereby certain unreasonable risks may be allowed to persist for a limited period) or EPA is addressing a persistent, bioaccumulative, and toxic substance as set forth in TSCA section 6(h), the standard for an adequate rule under TSCA section 6(a) is that it regulates "so that the chemical substance or mixture no longer presents" unreasonable risks under the conditions of use. 15 U.S.C. 2605(a). Prior to the 2016 amendment of TSCA, EPA completed risk assessments that were limited to selected uses of chemical substances. The amended TSCA authorizes EPA to issue TSCA section 6 rules that are not comprehensive of the conditions of use, so long as they are consistent with the scope of such pre-amendment risk assessments. 15 U.S.C. 2625(l)(4). But EPA has interpreted the amended TSCA as requiring that forthcoming risk evaluations encompass all manufacture, processing, distribution in commerce, use, and disposal activities that the Administrator determines are intended, known or reasonably foreseen."	Y	N	N	N	N	N	N	N	N	N	N
219	Healey_CommentAugust72018	1	Other, Exposure	N/A	Following EPA's denial of the petition, the petitioners challenged the denial in federal district court. EPA moved to dismiss the federal court challenge because the petitioners did not address conditions of use other than fluoridation of drinking water. As EPA stated in its denial of the petition: "Rather than comprehensively addressing the conditions of use that apply to a particular chemical substance, the petition requests EPA to take action on a single condition of use (water fluoridation) that cuts across a category of chemical substances (fluoridation chemicals)." The court denied EPA's motion, recognizing that a citizen petitioner under Section 21 of TSCA need not evaluate all conditions of use for the chemical substance at issue. However, for TSCA Section 6 chemical substance risk evaluations by EPA, as opposed to Section 21 determinations regarding citizens' petitions, TSCA requires the agency comprehensively to address the conditions of use that apply to that particular substance. EPA's retreat from its broad interpretation of the conditions of use that must be considered under Section 6 of TSCA is both contrary to law and represents what appears to be a mere impermissible convenient reinterpretation of the statute by the agency to avoid adequately regulating chemical substances under Section 6.	Y	N	N	N	N	N	N	N	N	N	N
220	Healey_CommentAugust72018	1	RegNex, Policy	2.5.3	2. Risk Evaluations Must Assess Exposure Pathways For All Uses, Including Those Addressed Under Other Statures. EPA is also failing to identify properly the conditions of use by not considering exposures resulting from uses of the chemical purportedly addressed within the context of other statutory schemes.	Y	N	N	N	N	N	N	N	N	N	N
221	Healey_CommentAugust72018	1	RegNex, Human Health, Eco Health	2.2, 2.5.3	EPA claims in the Problem Formulation for perchloroethylene that it is not excluding any conditions of use for the chemical,[p. 22] while ignoring in the risk evaluation significant pathways for exposure to that chemical, finding that the chemical is adequately regulated under other identified regulatory programs under other statutes. [p. 59] While the protections under other regulatory schemes may reduce exposure potential, it is EPA's charge under TSCA to eliminate unreasonable risk to human health and the environment posed by the chemical, a mandate that only can be satisfied if EPA includes in its risk evaluations all known exposure pathways assessed cumulatively. Without a sound evaluation of those exposure pathways, whether potentially addressed by other regulatory schemes or not, EPA cannot fulfill its mandate to evaluate and eliminate unreasonable risks posed by these chemicals. Perchloroethylene, known as perc, is a dry cleaning solvent and is also used as a metal degreaser, a chemical intermediate and an ingredient in consumer products, such as automotive aerosol parts cleaners and degreasers. Perc has been reported to be the chemical most widely found in groundwater contamination at Superfund sites. Acute exposures to perchloroethylene have been associated with dizziness, confusion, headache, nausea, and irritation of the eyes and mucous tissue, while exposure to extremely high levels of perc may lead to unconsciousness and, in extreme cases, death from respiratory depression. Long term exposure to perc may cause liver, kidney or central nervous system damage, and perc has been characterized by the International Agency on Research on Cancer (IARC) as "probably carcinogenic to humans."	N	N	N	Y	N	N	N	N	N	N	N

222	Healey_CommentAugust72018	1	RegNex, Exposure	2.5.3.2	In the perchloroethylene Problem Formulation, Section 2.5.3.2, EPA carves out recognized exposure pathways from its analysis: Pathways That EPA Does Not Expect to Include in the Risk Evaluation Exposures to receptors may occur from industrial and/or commercial uses, industrial releases to air, water or land; and other conditions of use. As described in [this section], pathways under other environmental statutes, administered by EPA, which adequately assess and effectively manage exposures and for which long-standing regulatory and analytical processes already exist will not be included in the risk evaluation." [p. 59] The Problem Formulation then identifies the statutory schemes under which perchloroethylene is regulated: (i) the Clean Air Act (regulates perc as a hazardous air pollutant and prescribes technology-based standards and other limitations as required for stationary source emissions of perchloroethylene); (ii) the Safe Drinking Water Act (sets Maximum Contaminant Levels for perc in drinking water); (iii) the federal Clean Water Act (perchloroethylene is a "priority pollutant" requiring the adoption of numeric criteria and discharge permit limits to protect surface water quality and perchloroethylene has been identified in biosolids reviews that EPA says it plans to address in the future); and (iv) the Resource Conservation and Recovery Act (RCRA) (perchloroethylene is a listed hazardous waste, the treatment, storage, and disposal of which is regulated under the act).	N	N	N	Y	N	N	N	N	N	N	N
223	Healey_CommentAugust72018	1	RegNex, Exposure	N/A	However, EPA's charge under TSCA is to evaluate the risks from the full range of exposures in the circumstances under which the chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of, to determine whether the chemical substance presents an unreasonable risk of injury to health or the environment. Section 6(b)(4)(A) of TSCA; 15 U.S.C. § 2605(b)(4)(A) and Section 3(4) of TSCA; 15 U.S.C. § 2602(4)	Y	N	N	N	N	N	N	N	N	N	N
224	Healey_CommentAugust72018	1	Exposure/RegNex/Policy	2.5.3.2	Even if EPA's actions under its separate regulatory programs for perchloroethylene described above serve to meet each statute's requirements for protections under that statute, relying on each of those individual mandates for addressing the chemical as a pollutant (mandates designed to reduce impacts and exposures but not eliminate them), provides no assurance that TSCA's mandate for eliminating unreasonable risks will be met because the potential cumulative effect of exposures to the chemical across environmental media must be considered in its evaluations.	N	N	N	Y	N	N	N	N	N	N	N
225	Healey_CommentAugust72018	1	RegNex, Exposure	N/A	The standard for an adequate rule under TSCA section 6(a is that it regulate so that the chemical substance no longer presents unreasonable risks to public health and the environment, and it necessarily follows that EPA must evaluate the potential for exposure and risk associated with perchloroethylene being regulated under those schemes, and make appropriate TSCA regulatory determinations that account for those anticipated exposures, in order to regulate the chemical as Section 6 requires.	Y	N	N	N	N	N	N	N	N	N	N
226	Healey_CommentAugust72018	1	RegNex, Exposure	2.4.2.2	This flaw is also highlighted in the Problem Formulation of the Risk Evaluation for Methylene Chloride. 106 Methylene chloride is a chlorinated solvent commonly used as a metal degreaser, a chemical intermediate, a reaction extraction solvent, a paint stripper, and as a component of adhesives, found in consumer products that can be purchased at local automotive and hardware stores. Methylene chloride exposure can result in serious adverse health effects, and high, short-term exposures can be lethal, with its extreme volatility making it especially dangerous because unsafe airborne concentrations can readily be created through evaporation. As noted in the Problem Formulation, in its IRIS (Integrated Risk Information System) assessment, "EPA concluded that methylene chloride is 'likely to be carcinogenic in humans by all routes of exposure.'"[p. 46] The International Agency for Research on Cancer (IARC) classifies methylene chloride as a possible human carcinogen (Group 2B), and the National Toxicology Program of the U.S. Department of Health and Human Services classifies methylene chloride as "reasonably anticipated to be a human carcinogen." Footnote: 106 Note that on May 10, 2018, EPA announced its intention to finalize a rule making for methylene chloride. See EPA Announces Action on Methylene Chloride, U.S. ENVTL. PROT. AGENCY, https://www.epa.gov/newsreleases/epa-announces-action-methylene-chloride (last accessed Jul. 10, 2018). To our knowledge, EPA has not specified the action it plans to take and it is not clear whether EPA plans to adopt a ban of the chemical and if so, the extent of such ban. However, the Environmental Defense Fund has argued that to protect public health, the final rule should "Ban distribution in commerce and use of methylene chloride for paint and coating removal; extend to both consumer and commercial uses . . . ; not provide exemptions based on training, labeling or use of protective equipment; be finalized and implemented quickly; [and] require full compliance within as short as possible a period." See Richard Denison, Ph.D., Lead Senior Scientist, Environmental Defense Fund, Critical 'blanks' in EPA's methylene chloride announcement need to be filled in if it is to be health protective, May 10, 2018, http://blogs.edf.org/health/2018/05/10/critical-blanks-in-epas-methylene-chloride-announcement-need-to-be-filled-in-if-it-is-to-be-health-protective/ (last accessed Jul. 10, 2018). Home Depot, Loews, and Sherwin-Williams have committed to phasing out methylene chloride and NMP based paint strippers by the end of 2018. See Chemical Watch, Campaigners secure third paint stripper victory with Home Depot," Jun. 20, 2018, https://chemicalwatch.com/67874/campaigners-secure-third-paint-stripper-victory-with-home-depot (last accessed Jul. 10, 2018).	N	N	N	N	N	N	N	Y	N	N	N
227	Healey_CommentAugust72018	1	RegNex, Exposure	2.3.3	Methylene chloride is a widespread contaminant in our environment. For example, the problem formulation notes that "[d]ata compiled between 1992 and 2001 from NAWQA [the U.S. Geological Survey's National Water Quality Assessment Program] showed methylene chloride to be found in 6% of all ground water and surface water samples, with occurrences more common in surface water. Methylene chloride was detected in 20% of sediment samples in the [EPA] STORET database." [p. 36] And yet, EPA plans to exclude exposure pathways for methylene chloride that allegedly are addressed under other statutes although these pathways have been identified for regulation precisely because they are known or suspected to pose a serious concern. For example, EPA plans to exclude from consideration: (i) "stationary source releases of methylene chloride to ambient air," as methylene chloride is regulated as a hazardous air pollutant (HAP) under the Clean Air Act; and (ii) exposures through drinking water because these are regulated under the Safe Drinking Water Act. EPA also plans to exclude from consideration "methylene chloride-based extraction solvents for oils, waxes, fats, spices, and hops" because they "meet the definition of food additive" under the Federal Food, Drug and Cosmetic Act, and so would ignore potentially significant exposure pathways. By excluding consideration of exposures to methylene chloride through drinking water and other pathways of chronic exposure, it will not be possible for EPA to conduct an adequate risk evaluation for methylene chloride under Section 6 of TSCA. Through this misguided approach of ignoring uses that are subject to other regulatory schemes, EPA has essentially eliminated from consideration those pathways that Congress has prioritized for regulation to date.	N	N	N	N	N	N	N	Y	N	N	N

228	Healey_CommentAugust72018	1	Exposure	2.2, 2.5	The approach to science expressed by EPA as reflected in the Problem Formulations fails to satisfy TSCA's "best available science" standard for the quality of data that EPA must consider in preparing its risk evaluation, and TSCA's "weight of scientific evidence" standard for decision making under Section 2605. Under TSCA, Congress expressly required EPA to engage in science-based actions to prevent unreasonable risk of injury to health or the environment as result of exposures to hazardous chemical substances: (h) Scientific standards: "In carrying out section [2605] of this title . . . the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science . . . ." (i) Weight of scientific evidence: "The Administrator shall make decisions under section [2605] of this title based on the weight of the scientific evidence." (k) Reasonably available information: "In carrying out sections 2603, 2604, and 2605 of this title, the Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." EPA is failing to account for some of the most significant, generally recognized pathways of exposure in the Problem Formulations. It follows that it is impossible for EPA to satisfy the "best available science" standard because it is choosing to put on blinders and ignore some of the most meaningful data with respect to risks of exposure to the chemical substance.	Y	N	N	N	N	N	N	N	N	N	N
229	Healey_CommentAugust72018	1	Exposure, Policy	2.2, 2.5	Additionally, in its evaluation of uses in the Problem Formulations EPA fails to satisfy its statutory duties to review all reasonably available information. The Problem Formulations are rife with examples of instances where it appears that EPA stopped short of complete data collection, failing to satisfy its statutory obligation to consider the information "reasonably available" to it. Unfortunately, notwithstanding Congress's express requirement that EPA use the "best available science" in regulating toxic chemicals, the Problem Formulations on their face make it impossible for EPA to conduct the risk evaluations as required in this regard. The recent overhaul of TSCA was designed to address the recognized failures of traditional risk assessment to consider the big picture of toxic chemicals exposures and address the landscape of the many uses and exposure pathways affecting different people in different ways. TSCA, as amended by the Lautenberg Act, addresses this by mandating comprehensive risk evaluations in which EPA reviews chemical substances broadly in the context of the chemical substances' known, intended, and reasonably foreseen uses across the full spectrum of potentially exposed populations. The Problem Formulations, which would restrict EPA's reviews to certain uses and exposures that do not reflect the pathways through which people and the environment are affected by these chemical substances, will not meet the express purpose of TSCA as amended and should be abandoned in this regard.	Y	N	N	N	N	N	N	N	N	N	N
230	Healey_CommentAugust72018	1	Other, Policy	2.2, 2.5	We believe that the risk evaluations that EPA proposes to conduct for the Initial Ten TSCA Chemicals, in which the agency plans to consider only a subset of the uses for which the chemical substances are intended, known or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed, fails to satisfy the requirements for risk evaluations under TSCA. We therefore urge EPA to issue revised Scopes of the Risk Evaluation for each of the Initial Ten TSCA Chemicals to address the concerns we raise above regarding the agency's unlawful approach to identifying the conditions of use as that term is properly understood under TSCA and to ensure that the data EPA considers in its risk evaluations satisfies TSCA's "best available science" standards. After conducting appropriate risk evaluations, we expect EPA will impose new protective restrictions, and in some cases bans, for at least some of the Initial Ten TSCA Chemicals.	Y	N	N	N	N	N	N	N	N	N	N
231	ACOEMCommentAugust82018	1	General	N/A	The American College of Occupational and Environmental Medicine (ACOEM) is pleased to respond to the EPA's request for comments about its planned chemical evaluation for 1-bromopropane. EPA is requesting any information from the public on 1-bromopropane both domestically and internationally. ACOEM represents more than 4,000 physicians and other health care professionals specializing in the field of occupational and environmental medicine (OEM). Founded in 1916, ACOEM is the nation's largest medical society dedicated to promoting the health of workers through preventive medicine, clinical care, research, and education. A dynamic group of physicians encompassing specialists in a variety of medical practices is united via the College to develop positions and policies on vital issues relevant to the practice of preventive medicine both within and outside of the workplace.	N	Y	N	N	N	N	N	N	N	N	N
232	ACOEMCommentAugust82018	1	Exposure, PESS	N/A	We recognize that the literature on the health effects of exposure to 1-bromopropane is extensive. Additionally, ACOEM recognizes that occupationally exposed workers represent a particular susceptible subpopulation, deserving of special scrutiny. At present OSHA has not set a permissible exposure limit for occupational exposures to 1-bromopropane, although ACGIH (and what other authority, NIOSH?) have recommended that such occupational exposures be rigorously controlled, with a recommended TLV of 0.1 ppm. NIOSH has proposed a Recommended Exposure Limit of 0.3 ppm. In 2009, Cal/OSHA set a permissible exposure of 5 ppm, for occupational exposures within California. The National Toxicology Program has listed 1-bromopropane as reasonably anticipated to be a human carcinogen. ACOEM urges EPA to consider both the cancer and non-cancer health effects resulting from exposure to 1-bromopropane, particularly in occupationally exposed populations where exposure is likely to be highest.	N	Y	N	N	N	N	N	N	N	N	N
233	Anonymous1CommentAugust142018	1	General	N/A	Obviously this is a horrible idea even thinking that we should allow asbestos in anything. It's not even close to a good idea. You're the EPA. Clean air, clean water, clean everything and anything. Progress involves moving forward with cleaner solutions for everything. That involves moving away from things we know are harmful. Asbestos is one of those things. Please hold corporations and polluters more responsible. Thank you. [comment was downloaded from 1-BP docket]	N	N	N	N	N	N	N	N	N	N	Y
234	Anonymous2CommentAugust142018	1	General	N/A	This is a product long known to have harmful effects and should be banned. We should move on to better and safer products not revisit them.	N	Y	N	N	N	N	N	N	N	N	N
235	Anonymous3CommentAugust132018	1	General	N/A	I resent the fact that the EPA has failed in the past year and a half to protect American taxpayers from dangerous chemicals. Please do not permit 1-Bromopropane to be used in the US. Thank you!	N	Y	N	N	N	N	N	N	N	N	N
236	ICLCommentJuly182018	2	Human Health	2.4.2.2	ICL would like the Agency to consider the outcome of the following study when evaluating the genotoxicity data of the substance. We would like to emphasis the rational and justification of doses selection. ICL has recently obtained the study to support n-Propyl Bromide (1-Bromopropane) REACH registration. The title of the study is identified below: In Vivo Mutation Assay of n-Propyl Bromide at the cII Locus in Big Blue® Transgenic B6C3F1 Mice Exposed via Whole-Body	N	Y	N	N	N	N	N	N	N	N	N
237	ICLCommentJuly182018	2	Human Health	2.4.2.2	A copy of the study's summary is attached with this comment. ICL submitted a copy of the full report to EPA for the consideration of the TSCA Work Plan Chemical Risk Assessment Review for 1-Bromopropane (n-Propyl Bromide). ICL would also like to emphasize that the doses of the OECD 488 study by ICL followed the doses used in the NTP study for the product, as can be seen in the following extract from the final report: "The test substance, n-propyl bromide, was administered via whole-body inhalation exposure for 6 hours per day for 28 consecutive days to 3 groups (Groups 2, 3 and 4) of female BigBlue® B6C3F1 mice. Target exposure concentrations were 62.5, 125 and 250 ppm for Groups 2, 3 and 4, respectively." "3.7.3 Justification for Selection of Exposure Route, Exposure Levels and Sex of Animals The dose route, target exposure concentrations and exposure regimen (6 hours per day for 7 days per week) for a 28-day period were selected by the Sponsor's Representative and are consistent with those recommended in OECD Test Guideline 488 (OECD, 2013). The National Toxicology Program (NTP) report on 1-bromopropane showed an increase in lung tumors with the highest incidence in female mice in a 2-year cancer study (NTP, 2013). The NTP study was conducted using the inhalation route at test concentrations of 62.5, 125 and 250 ppm. In order to replicate the tumorigenic dose levels and exposure conditions, the same approach was taken for this study with the modification of exposure using the OECD TG488-specified 7 day/week exposure, 28 days dosing regimen. The design is sufficient to permit genetic damage and fixation of the damage into detectable mutants."	N	Y	N	N	N	N	N	N	N	N	N

238	ICLCommentJuly182018	2	Human Health	2.4.2.2	The experimental data shows clearly that treatment with n-Propyl Bromide did not cause statistically elevated mutant frequencies at the cII gene in liver and lungs of Big Blue® female mice. The positive control treatment with ENU produced statistically significant increases in mutant frequencies for both tissues tested, demonstrating the utility of the test system to detect and quantify induced mutants following exposure to a known direct acting mutagen. The study design and results obtained met protocol-specified assay acceptance criteria and were consistent with the study requirements of OECD TG 488 for transgenic rodent mutation assays, supporting the conclusion that n-Propyl Bromide is negative for the induction of cII mutants in liver and lungs of Big Blue® female mice under the conditions of testing. Therefore, it can be concluded that the carcinogenic pathway of this substance is not genotoxic, and that it depends on exposure threshold. If you have any questions or need additional information, please feel free to contact us.	N	Y	N	N	N	N	N	N	N	N	N
239	ACOEMCommentAugust82018	1	General	N/A	The American College of Occupational and Environmental Medicine (ACOEM) is pleased to respond to the EPA's request for comments about its planned chemical evaluation for carbon tetrachloride (CCl4). EPA is requesting any information from the public on carbon tetrachloride (CCl4), both domestically and internationally. ACOEM represents more than 4,000 physicians and other health care professionals specializing in the field of occupational and environmental medicine (OEM). Founded in 1916, ACOEM is the nation's largest medical society dedicated to promoting the health of workers through preventive medicine, clinical care, research, and education. A dynamic group of physicians encompassing specialists in a variety of medical practices is united via the College to develop positions and policies on vital issues relevant to the practice of preventive medicine both within and outside of the workplace.	N	N	N	N	N	N	Y	N	N	N	N
240	ACOEMCommentAugust82018	1	Exposure	2.3, 2.4	We recognize that the literature on the health effects of exposure to carbon tetrachloride (CCl4) is extensive and that the general public's exposure to this substance has been decreasing. Additionally, ACOEM recognizes that occupationally exposed workers represent a particularly susceptible subpopulation, which continues to have active exposure to CCl4 and is deserving of special scrutiny. It is estimated that over 58,000 workers are exposed to CCl4 . OSHA's current permissible exposure limit (PEL) for PCE is 10 ppm for Federal OSHA. We urge EPA to consider all sources of exposure to CCl4 in potentially exposed workers to assure that cumulative exposures from occupational uses, from ambient air, and/or from drinking water do not exceed an acceptable level.	N	N	N	N	N	N	Y	N	N	N	N
241	ACOEMCommentAugust82018	1	Fate, Human Health	2.3, 2.4	In addition, ACOEM is concerned about the environmental fate of CCl4 released into the environment, particularly into ground water where it may linger for many years. Accordingly, ACOEM urges EPA to consider both the cancer and non-cancer health effects resulting from exposure to CCl4, particularly in occupationally exposed populations, where exposure is likely to be highest. Furthermore, given the troubling worldwide record of environmental CCl4 contamination, particularly involving groundwater, ACOEM encourages EPA to include in its chemical evaluation the environmental fate and environmental impacts of CCl4 use, both from intended uses as well as from uses that may be unintended but are reasonably foreseeable.	N	N	N	N	N	N	Y	N	N	N	N
242	Anonymous1August142018	1	General	N/A	This is a product long known to have harmful effects and should be banned. We should move on to better and safer products not revisit them.	N	N	N	N	N	N	Y	N	N	N	N
243	ACOEM_CommentAugust82018	1	General	N/A	The American College of Occupational and Environmental Medicine (ACOEM) is pleased to respond to the EPA's request for comments about its planned chemical evaluation for methylene chloride. EPA is requesting any information from the public on methylene chloride both domestically and internationally. ACOEM represents more than 4,000 physicians and other health care professionals specializing in the field of occupational and environmental medicine (OEM). Founded in 1916, ACOEM is the nation's largest medical society dedicated to promoting the health of workers through preventive medicine, clinical care, research, and education. A dynamic group of physicians encompassing specialists in a variety of medical practices is united via the College to develop positions and policies on vital issues relevant to the practice of preventive medicine both within and outside of the workplace.	N	N	N	N	N	N	N	Y	N	N	N
244	ACOEM_CommentAugust82018	1	Exposure, Human Health	2.3, 2.4	We recognize that the literature on the health effects of exposure to methylene chloride is extensive. Additionally, ACOEM recognizes that occupationally exposed workers represent a particularly susceptible subpopulation, deserving of special scrutiny. We further recognize that OSHA's current rule for exposure to methylene chloride for general industry as well as the maritime and construction trades is likely to be protective for non-cancer health effects, if followed by employers. However, the current PEL for methylene chloride (25 ppm, or 87 mg/cu m, as an 8-hour time-weighted average) would theoretically expose a worker to as much 480 mg of methylene chloride per day, assuming a breathing rate of 10 cu meters per 8-hour shift and an absorption factor of about 55%. Exposures in this range over a lifetime would impose on such exposed workers an incremental cancer risk exceeding one chance in a hundred, taking account of the current cancer potency estimates for methylene chloride.	N	N	N	N	N	N	N	Y	N	N	N
245	ACOEM_CommentAugust82018	1	Exposure, PESS, Human Health	2.3, 2.4	In addition, ACOEM is concerned about the multiple reports of fatal occupational exposures to methylene chloride, resulting from employers and employees failing to adhere to current OSHA rules and standard practices for the safe use of methylene chloride in paint-stripping and other refinishing operations. ACOEM would like to see a sharp reduction in exposures to methylene chloride in workers and members of the general population who strip paint. Accordingly, ACOEM urges EPA to consider both the cancer and non-cancer health effects resulting from exposure to methylene chloride, particularly in occupationally exposed populations, where exposure is likely to be highest.	N	N	N	N	N	N	N	Y	N	N	N
246	UCSF_CommentJune252018	2	General	N/A	I am writing to request a correction to the May 2018 EPA document "EPA's Responses to Public Comments Received on the Scope Documents for the First Ten Chemicals for Risk Evaluation under TSCA". On pg. 15, in response 16, comments are incorrectly attributed to the UCSF Program on Reproductive Health and the Environment (PRHE). I am pasting the text from the document below and attaching the UCSF PRHE comments 0741-0057 as downloaded from the 1-Bromopropane docket. UCSF PRHE's comments did not recommend or reference the "Beyond Science and Decisions" project. [pasted information]: Other 16. One commenters shared information on the "Beyond Science and Decisions" project, a risk methods compendium as a resource for regulators and scientists on key considerations for applying selected dose-response techniques for various problem formulations, with suggested techniques and resources (0741-0057). Response: Thank you for this comment and for the suggested resources. We did recommend that EPA use the risk assessment approaches, methods and principles in the National Academies of Sciences report "Science and Decisions: Advancing Risk Assessment" which we reference multiple times in our comments. I would appreciate if EPA could respond to this letter, correct this error immediately and issue a revised version of the "EPA's Response to Public Comments" document. Please do not hesitate to contact me with any questions.	Y	Y	N	N	N	N	N	N	N	N	N

247	UCSF_CommentJune 252018	2	General	N/A	These comments are submitted on behalf of the undersigned academic, scientists, and clinicians. We declare collectively that we have no direct or indirect financial or fiduciary interest in any chemical under consideration in these risk evaluations. The co-signers' institutional affiliations are included for identification purposes only and do not necessarily imply any institutional endorsement or support, unless indicated otherwise. We appreciate the opportunity to provide written comments on the scope of risk evaluations for the first ten chemical substances for risk evaluations pursuant to the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety of the 21st Century Act (Lautenberg TSCA). Collectively, these chemicals represent an aggregate production volume of more than 1 billion pounds a year in 2015. Some of these chemicals have assessments, and in some cases even restrictions, under other federal programs – but none of these other programs has the mandate given to EPA under the new TSCA: to comprehensively evaluate chemicals and ensure that they do not pose an unreasonable risk to human health and the environment, with special consideration to those most vulnerable amongst us. Therefore, the task ahead for EPA is critical.	Y	N	N	N	N	N	N	N	N	N	N
248	UCSF_CommentJune 252018	2	General	N/A	These first ten evaluations are also consequential because they will be precedent setting for the implementation of evaluation of science under TSCA. The consequent health impacts of EPA's decisions – for better or worse – will be borne by generations of American children, workers, families, and communities. With so much at stake, we welcome EPA's engagement with the public in this process and we offer EPA concrete approaches to embed the most current scientific principles in its methods to assess the hazards and risks of environmental chemicals.	Y	N	N	N	N	N	N	N	N	N	N
249	UCSF_CommentJune 252022	2	General/Exposure/PESS/Systematic Review	N/A	Our comments address the following main points: 1. EPA should improve its literature search and systematic review strategies to strengthen its evaluations and increase transparency. 2. EPA needs to consider aggregate exposure within and across populations; otherwise it will underestimate risk. Aggregate exposure should include legacy uses, uses where a chemical is present as a contaminant or by-product, and uses already assessed by EPA. 3. EPA appropriately identifies factors to consider to identify populations subject to greater exposures. EPA should also address susceptible sub-populations, following recommendations from the National Academies of Sciences (NAS) to identify susceptible sub-populations based on established extrinsic and intrinsic factors that increase vulnerability. 4. EPA should rely on existing IRIS assessments for hazard identification. Moving forward, EPA should complete hazard identification or add additional studies only through a systematic review process, which integrates animal, human and mechanistic evidence as recommended by the recent NAS report. 5. For risk characterization, EPA should use defaults and methods that account for the full range of risks in the population and that will form the basis of decisions that protect the public's health. 6. Confidential Business Information (CBI) claims should not be used to obscure critical data and information from the public.	Y	N	N	N	N	N	N	N	N	N	N
250	UCSF_CommentJune 252021	2	General	N/A	We are appreciative of the opportunity to provide public input and we look forward to continuing to participate in such opportunities in the near future. Please do not hesitate to contact us with any questions regarding these comments.	Y	N	N	N	N	N	N	N	N	N	N
251	UCSF_CommentJune 252025	2	Exposure	2.2.2	2. EPA needs to consider aggregate exposure within and across populations; otherwise it will underestimate risk. Aggregate exposure should include legacy uses, uses where a chemical is present as a contaminant or by-product, and uses already assessed by EPA. In general, EPA is proposing to consider three populations for exposure assessment: 1) Occupational users and non-users; 2) consumers and bystanders; and 3) general population. We strongly recommend that EPA calculate the aggregate exposures within and across these populations-- risk will be underestimated if it does not include these real-world exposures. Exposures within a population should also be aggregated (rather than considered in isolation) in order to estimate the general population's actual exposure to the chemical—for example, through exposures from food, water and air.	Y	N	N	N	N	N	N	N	N	N	N
252	UCSF_CommentJune 252026	2	Exposure	2.2.2	Further, as shown in the Figure below, exposures must also be aggregated across populations. Consumers and workers are part of the general population – that is, since workers and consumers also eat food and drink water, they will have the same exposures as the general population, in addition to the anticipated exposures on-the-job or from consumer products. Some workers will also be consumer product users, so they have the potential to face general, consumer product, and on-the-job exposures. These specific exposure scenarios must be accounted for in EPA's exposure estimation to ensure that such individual exposures are adequately considered and integrated into the risk assessment. [p. 10 Figure Legend: EPA must assess aggregate exposures within and across all the populations for accurate exposure assessment; Figure depicts the three populations noted within a circle and possible exposures (i.e., food, water, air, products.) The consumers and bystanders population and workers and non-users population are individually encircled but the circles overlap]	Y	N	N	N	N	N	N	N	N	N	N
253	UCSF_CommentJune 252027	2	Exposure	2.2	In the Introduction section of the chemical Scope documents [Section 1], EPA states that it "may consider background exposures from legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses." This falls short of the analysis required under Lautenberg TSCA. It is critical that EPA consider ongoing exposures from legacy uses and disposal, and includes these as part of the aggregate exposure assessment. Asbestos and HBCD are two examples of this, as they have enormous volumes in place in buildings and existing infrastructure. The Healthy Building Network estimates there are 66 million- 132 million pounds (30,000-60,000 metric tons) of HBCD in insulation in existing buildings —these reservoirs in-place are and will continue to be critical sources of ongoing exposures. HBCD was also used in cars and furniture, which are long-lived consumer items that will continue to contribute to ongoing exposures for years to come.	Y	N	N	N	N	Y	N	N	N	N	Y
254	UCSF_CommentJune 252028	2	Exposure	2.2	Another example is 1,4-dioxane, which was historically used as a chemical stabilizer for chlorinated solvents. Many groundwater aquifers are contaminated with 1,4-dioxane, and the extent of legacy contamination of groundwater is likely underestimated. Also, 1,4-dioxane occurs in a wide variety of products including personal care products, detergents, waxes, and antifreeze, and 1,4-dioxane is a byproduct in manufacturing processes involving ethylene oxide, such as the production of polyethylene terephthalate (PET), polyester, and surfactants. The use and disposal of 1,4-dioxane has led to past environmental contamination which contributes to on-going exposures. The physical and chemical properties of 1,4-dioxane render it a persistent and highly mobile water contaminant: it is highly miscible in water. Exposures via drinking water are documented back to the 1980s and continue today. Results from EPA's Third Unregulated Contaminant Monitoring Rule (UCMR3) highlight that over 13% of 4,905 public drinking water systems serving >10,000 people had concentrations of 1,4-dioxane above the EPA Reference Concentration of 0.35 ppb 1,4-dioxane. Furthermore, the UCMR3 results do not capture exposures in communities served by small public drinking water systems serving <10,000 people. Approximately 27% of the US population is served by small public drinking water systems. Thus, it will be critical for EPA to consider the population's current exposure to 1,4-dioxane via sources like drinking water as part of their assessment for health risks.	N	N	Y	N	N	N	N	N	N	N	N
255	UCSF_CommentJune 252029	2	Exposure	2.2	When a chemical is present in products or media as a contaminant/ by-product, EPA needs to include and assess these exposures. We strongly recommend against ignoring or discounting these potential exposures routes.	Y	N	N	N	N	N	N	N	N	N	N
256	UCSF_CommentJune 252029	2	Exposure	2.2	For example, EPA proposes to exclude from consideration conditions of use of 1,4-dioxane when it is present as contaminant in a wide variety of items, including household detergents, cosmetics/ toiletries, and foods. [p. 21 of Scope] This exclusion is not scientifically justified. Cosmetics and personal care products have the potential to contribute significantly to exposures, since people are applying them directly to their bodies, often multiple times per day, every day.	N	N	Y	N	N	N	N	N	N	N	N

257	UCSF_CommentJune 252030		2	Exposure, RegNex, Policy	2.2	Finally, in the exposure assessments for methylene chloride [p. 30 of Scope], N-methylpyrrolidone [pp. 19-20 of Scope] and trichloroethylene [p. 27 of Scope], EPA is proposing to exclude uses it already assessed. We agree that EPA does not need to re-assess these uses; these evaluations have been completed and finalized. However, unless and until such uses are banned, the exposures from these uses continue. Therefore, the new risk evaluations need to consider the contributions of these uses to exposures by using the exposure values from the previous assessments.	Y	N	N	N	N	N	N	Y	Y	Y	N
258	UCSF_CommentJune 252031		3	Exposure, PESS	2.6.1	For the occupational exposure analysis plan, EPA states it will "Consider and incorporate applicable engineering controls and/or personal protective equipment into exposure scenarios." However, these are not realistic assumptions nor are they appropriate for public health protection. EPA's own research shows that the primary factors influencing whether a user understands label information are the users' literacy and numeracy, which frequently correlate with the users' education and income. Therefore, people with less education, lower income, and less advanced literary skills will be the most likely to not understand label instructions. These individuals already disproportionately bear the burden of exposures to multiple environmental hazards and the resulting health impacts; thereby placing further burden on this already stressed susceptible subpopulation. Further, appropriate personal protective equipment (PPE) for workers is often not provided by employers, or may not be fitted or working properly. When evaluating occupational exposures, EPA needs to take into consideration all potential and feasible routes of exposure, and should not exclude exposure routes based on assumptions of PPE and/ or exposure controls in place. These controls are not guaranteed and may change in the future, so to assume zero exposure via these routes would be inappropriate and a failure to adequately ensure health protections, especially for susceptible sub-populations as required by the Lautenberg TSCA.	Y	N	N	N	N	N	N	N	N	N	N
259	UCSF_CommentJune 252032		2	Exposure	2.2, 2.3, 2.6	In summary, EPA needs to account for all the sources of exposure or it will underestimate risk for all 10 chemicals. When analyzing aggregate exposures, "sentinel exposure" may be considered simultaneously, where appropriate. However, these are not mutually exclusive and EPA should not incorporate sentinel to the exclusion of aggregate.	Y	N	N	N	N	N	N	N	N	N	N
260	UCSF_CommentJune 252033		2	PESS	2.3.5	3.EPA appropriately identified factors to consider to identify populations subject to greater exposures. EPA should also address susceptible sub-populations, following recommendations from the National Academis of Sciences (NAS) to identifiy suscepitble sub-populations based on established extrinsic and intrinsic factors that increase vulnerability. In general, EPA proposes to consider workers and occupational non-users, consumer and by-standers, and other groups within the general population in proximity to conditions of use as sub-populations who experience greater exposures. In particular, EPA has appropriately identified people who live or work near manufacturing, processing, distribution, use or disposal sites as facing greater exposures. Such communities are often low income and/ or people of color, exposed to a disproportionate share of pollution, environmental hazards, social and economic stressors. Multiple exposures to chemical and non-chemical stressors collectively increase the risk of harm, combined with synergistic effects with other health stressors in their daily lives such as limited access to quality health care.	Y	N	N	N	N	N	N	N	N	N	N
261	UCSF_CommentJune 252035		2	PESS	2.3.5	EPA's risk evaluation needs to fully account for the reality of cumulative exposures, as recommended by the NAS in their Phthalates and Cumulative Risk report. As described below, EPA can use "default values" to account for cumulative exposures. In regards to greater susceptibility, EPA's considerations for addressing susceptibility vary considerably across the 10 chemicals. EPA should apply a consistent approach to addressing susceptibility across the 10 chemicals. The following are well-known factors that increase biologic sensitivity or reduce resilience to exposures, and these as well as other relevant factors should be standard considerations for all 10 chemicals to identify susceptible sub-populations: Intrinsic/ endogenous factors • Genetic polymorphisms/ genetics/ genetic makeup • Health status/ nutritional status/ disease status/ pre-existing conditions • Prenatal lifestage • Age Extrinsic factors • Multiple exposures/ co-exposures • Race/ ethnicity • Socioeconomic status (SES)	Y	N	N	N	N	N	N	N	N	N	N
262	UCSF_CommentJune 252036		2	PESS	2.3.5	For example, the prenatal lifestage is the most sensitive to developmental and reproductive toxicants, and women of child-bearing age should be considered as a susceptible sub-population for any chemicals with such hazards. Women of reproductive age are not specifically identified as a potential susceptible sub-population for pigment violet 29, TCE, NMP, PERC, or HBCD, even though EPA will consider reproductive and developmental toxicity hazards for these chemicals.	Y	N	N	Y	Y	Y	N	N	Y	Y	N
263	UCSF_CommentJune 252037		2	PESS	2.3.5	As discussed below, science-based defaults should be used to account for these and other susceptibilities, unless there is there is chemical-specific data available to support increasing or decreasing the default.	Y	N	N	N	N	N	N	N	N	N	N
264	UCSF_CommentJune 252044		2	PESS	N/A	5. For risk characterization, EPA should use defaults and methods that account for the full range of risks in the population and that will form the basis of decisions that protect the public's health. Defaluts: We strongly support the use of health protective defaults to incorporate factors that reflect the range of variability and susceptibility in the population to ensure risks are not underestimated. The importance of using protective science-based defaults was highlighted by the NAS in 2009. The default should be used for factors that are known to influence risk unless there is chemical-specific data that support increasing or decreasing it; when there is inadequate information to quantitatively assess inter- or intraspecies differences for a specific chemical, the defaults should be used. For example, EPA's defaults should include: • Inter-human variability, general • Inter-human susceptibility to carcinogens, adult • Inter-human susceptibility to carcinogens, early life (including prenatal) • Inter-human susceptibility to non-carcinogens, early life (including prenatal) • Animal findings are relevant to humans • Findings from one route of exposure are considered representative unless data show otherwise	Y	N	N	N	N	N	N	N	N	N	N
265	UCSF_CommentJune 252044		2	Other, PESS	N/A	EPA has relied on standard default values ("uncertainty" or "safety" factors) that have been applied across the board to various chemicals and health outcomes. But newer science demonstrates that EPA's typical safety factor of 10 is insufficient to account for variability due to life stage, genetics, underlying disease status, and external stressors that may be due to poverty or other difficult life conditions.	Y	N	N	N	N	N	N	N	N	N	N
266	UCSF_CommentJune 252044		2	PESS, Human Health, General	2.6	For cancer, the NAS recommended that EPA include a factor to account for human variability in response to carcinogens, as EPA's current approach inaccurately assumes that there is no variability in response. They found that a factor of 25- to 50- may account for the variability between the median individual and those with more extreme responses, and recommended 25 as a reasonable default value.	Y	N	N	N	N	N	N	N	N	N	N

267	UCSF_CommentJune 252044	3	PESS, Human Health	2.6	Similarly, EPA should increase or add factors that address cancer and non-cancer susceptibility during early life stages. While EPA does account for increased susceptibility to genotoxicants, it does not include the prenatal period or chemicals that can influence cancer through other mechanisms. California EPA's guidance incorporates factors to account for increased susceptibility for exposures that occur prenatally for carcinogens, non-mutagenic carcinogenic agents and non-carcinogens. Their literature review on differential susceptibility to carcinogens and non-carcinogens based on age and life stage derived age adjustment values for carcinogens which include the prenatal period and increased the default intraspecies uncertainty factors for non-carcinogens to 30 and 100 for specific endpoints such as asthma or neurotoxicity. At a minimum, EPA should use Cal EPA's age adjustment values and intraspecies uncertainty factors for incorporating age/early life susceptibility.	Y	N	N	N	N	N	N	N	N	N	N
268	UCSF_CommentJune 252044	2	PESS, Human Health	2.6	In general, developmental life stages, including the fetus, infancy, and childhood, are more vulnerable to chemical exposure and toxicity. However, typical EPA age-dependent adjustment factors account for other life stages but NOT fetal exposures. Recent studies have demonstrated differential expression and activity of metabolic enzymes such as Cytochrome P450 in fetal versus adult tissue, indicating potential lifestage-dependent variability in metabolic capabilities and greater vulnerability during fetal development not accounted for in current risk assessment practices. This is a critical point to address, as disruptions during fetal development have implications for health and disease in adulthood. EPA should evaluate this rich body of literature to identify the most up-to-date scientific knowledge regarding human variability and susceptibility and incorporate these scientifically-based default values in their assessments unless there are chemical-specific data supporting departing from the defaults. California EPA also developed child-specific risk values for chemicals (e.g., atrazine, lead, nickel, manganese, heptachlor) that specifically address routes of exposure and differences in susceptibility unique to children compared to adults. EPA should review these evaluations and incorporate these values as appropriate. Furthermore, a default guidance principle should be that animal findings are relevant to humans unless there is sufficient and compelling information to support otherwise.	Y	N	N	N	N	N	N	N	N	N	N
269	UCSF_CommentJune 252044	2	Other	2.6	Risk Estimates: EPA should not use MOE (margin of exposure) as an analysis method in the risk evaluation process moving forward. MOE is not an estimate of risk—it is a single number that is a version of the "bright line" approach like the Reference Dose (or Reference Concentration for inhalation doses). MOE is calculated by dividing the point of departure (e.g., LOAELs, NOAELs or BMDLs) by estimated exposure values, and this 'bright line' approach does not provide information about the magnitude of the risks above, at, or below this line. Further, it implies that there is a "safe" level of exposure below which no harm will occur. While this may be true for a select few chemicals, the NAS Science and Decisions report recognizes that this is not a valid assumption for all chemicals and has recommended moving away from such "bright line" approaches which do not establish risk estimates across the full range of exposures. Additionally, the MOE will not provide the necessary information for future analysis of risks and benefits that will be critical for decision-making on these chemicals. We recommend that EPA utilize available analytical methods such as PODs based on a BMD to develop quantified estimates of risk.	Y	N	N	N	N	N	N	N	N	N	N
270	UCSF_CommentJune 252044	2	Other	2.6	EPA appropriately states that a dose-response assessment will be conducted for all identified human health hazard endpoints. PODs should also be developed for every endpoint unless the data are insufficient to develop a model. For calculating cancer or non-cancer risks, we recommend always using a point of departure (POD) of a benchmark dose (BMD) at 1%. The POD should be based on a BMD calculation, not the NOAEL/LOAEL, unless the data are insufficient to model. EPA already recognizes the features that make BMDs superior: BMDs account for the shape of the dose–response function; are independent of study design, such as the space between dosing; and are comparable across chemicals.	Y	N	N	N	N	N	N	N	N	N	N
271	UCSF_CommentJune 252044	2	Other	2.6	Historically, for carcinogens that are direct mutagens or are associated with large human body burdens, EPA has assumed there is no threshold of effect. But the NAS Science and Decisions report highlights the science indicating that this linear presumption with no threshold is appropriate for the calculation of both cancer and non-cancer risks, and regardless of whether a carcinogen is a mutagen. For example, dose-response relationships can be linear at low dose when exposures contribute to an existing disease process, add to background processes and/ or exposures, and interact with interindividual variability or susceptibility. Science and Decisions recommends harmonizing cancer and non-cancer risk assessment approaches. Therefore, for calculating non-mutagen cancer or non-cancer risks based on a POD, EPA should use the same approach as for mutagens, which assumes a straight line from the POD. In fact, a linear relationship may actually underestimate risks for some chemicals where the dose-response curve is supra-linear.	Y	N	N	N	N	N	N	N	N	N	N
273	UCSF_CommentJune 252044	2	Other	N/A	6. Confidential Business Information (CBI) claims should not be used to obscure critical data and information from the public. Production volumes for both asbestos and pigment violet 29 have been claimed as CBI. Production volume is basic information about a chemical to which the public and scientists should have access. We urge EPA to move forward with substantiating such claims under the new TSCA.	Y	N	N	N	Y	N	N	N	N	N	Y
274	KemiraCommentJuly 252018	1	Exposure, Other	B.1.3	In an effort to provide additional information on how NMP may be used in the industrial applications, Kemira is pleased to provide the following comments regarding the Agency's scoping documents description of a reaction medium for polymerization reactions. nMethylpyrrolidone (nMP) is an industrial solvent that is used in a very narrow application. Specifically, it is the preferred sovent for phenothaizine (PTZ), the short-stop chemical for glacial acrylic acid (GAA) and glacial methacryic acid (GMA). In case of an uncontrolled polymerization within the storage tank, the PTZ can be injected in an attempt to stop this reaction and prevent a tank rupture. nMP provides for solution concentrations of up to 35%, is non-flammable and has a relatively low vapor pressure, making it ideal for this application. It is only to be used internally and we see no suitable replacement. There are two usage scenarios for this application. The first, is a 35% by weight PTZ and 65% nMP. The solution is delivered in drums and pumped into a small holding tank, usually located above the GAA storage tank. The handling operator is ideally suited in a chemical resistant jacket, gloves, goggles and a face shield.	N	N	N	N	N	N	N	N	Y	N	N
275	KemiraCommentJuly 252018	1	Exposure, Other	B.1.3.6	The second usage scenario is to purchase pure nMP and pure PTZ. A solution of approximately 10% PTZ by weight is then manually prepared by adding the PTZ to nMP in a mixing container. The solution is not easily formed so manual breakage of lumps and overnight mixing is required. As with the solution, the handling operator is ideally suited in a chemical resistant jacket, gloves, goggles and a face shield. The prepared solution is then pumped into the holding tank with the same handling precautions as above. Once in the holding tank, the solution may be periodically pumped out to allow servicing of instrumentation and equipment associated with the safety short-stop system. As before, the operator handling the material must be suited in a chemical resistant jacket, gloves, goggles and a face shield. The PTZ solution has a limited shelf life of about 5 years. As a result the solution must be periodically replaced with fresh material. This involves the same pumping and handling operations as above. This use scenario, of a polymerization inhibitor, will not become part of a commercialized finished product where residual nMPs can be measured; therefore no migration to consumer markets of concern is involved. Thank you for your review and consideration of these comments. Feel free to contact us with any questions	N	N	N	N	N	N	N	N	Y	N	N

276	ACOEMCommentAugust82018	1	General	N/A	The American College of Occupational and Environmental Medicine (ACOEM) is pleased to respond to the EPA's request for comments about its planned chemical evaluation for perchloroethylene (PCE). EPA is requesting any information from the public on perchloroethylene (PCE both domestically and internationally. ACOEM represents more than 4,000 physicians and other health care professionals specializing in the field of occupational and environmental medicine (OEM). Founded in 1916, ACOEM is the nation's largest medical society dedicated to promoting the health of workers through preventive medicine, clinical care, research, and education. A dynamic group of physicians encompassing specialists in a variety of medical practices is united via the College to develop positions and policies on vital issues relevant to the practice of preventive medicine both within and outside of the workplace.	Y	N	N	N	N	N	N	N	N	N	N
277	ACOEMCommentAugust82018	1	Exposure, RegNex, Human health	2.3.5	We recognize that the literature on the health effects of exposure to perchloroethylene (PCE) is extensive. Additionally, ACOEM recognizes that occupationally exposed workers represent a particularly susceptible subpopulation, deserving of special scrutiny. We further recognize that OSHA's current rule for exposure to PCE is likely not protective for neurological effects in exposed adults and is almost surely not protective for cancer and reproductive health effects.	N	N	N	Y	N	N	N	N	N	N	N
278	ACOEMCommentAugust82018	1	Exposure, Human Health	N/A	The National Toxicology Program classifies PCE as "reasonably anticipated to be a human carcinogen." OSHA's current permissible exposure limit (PEL) for PCE (100 ppm for Federal OSHA, or 678 mg/cu m, as an 8-hour time-weighted average) would theoretically permit a worker to be exposed to as much as 4,750 mg of trichloroethylene per day, assuming a breathing rate of 10 cu meters per 8-hour shift and an absorption factor of about 70%. Exposures in this range over a lifetime would impose an incremental cancer risk for exposed workers markedly exceeding one chance in a hundred, taking account of the current cancer potency estimates for PCE. By contrast, ACOEM applauds EPA's previous calculation of a Reference Concentration (RfC) for PCE of 0.04 milligrams per cubic meter based on neurotoxicity in occupationally-exposed adults. We urge EPA to consider all sources of exposure to PCE in potentially exposed workers to assure that cumulative exposures from occupational uses, from ambient air, and/or from drinking water do not exceed an acceptable level.	N	N	N	Y	N	N	N	N	N	N	N
279	ACOEMCommentAugust82018	1	Fate	2.3., 2.6.1	In addition, ACOEM is concerned about the fate of PCE released into the environment, whether in the form of surface-run off, release from storage tanks, or other unintended releases. The extent of persistent groundwater contamination with PCE has been documented in many parts of the nation.	N	N	N	Y	N	N	N	N	N	N	N
280	ACOEMCommentAugust82018	1	Human Health, PESS, Exposure	2.3.5, 2.6.1	Accordingly, ACOEM urges EPA to consider both the cancer and non-cancer health effects resulting from exposure to PCE, particularly in occupationally exposed populations for whom exposure is likely to be highest.	N	N	N	Y	N	N	N	N	N	N	N
281	ACOEMCommentAugust82018	1	Fate	2.3., 2.6.1	Furthermore, given the troubling worldwide record of environmental PCE contamination, particularly involving groundwater, ACOEM encourages EPA to include in its chemical evaluation the environmental fate and environmental impacts of PCE use, both from intended uses as well as from uses that may be unintended but are reasonably foreseeable.	N	N	N	Y	N	N	N	N	N	N	N
282	AnonymousCommentJuly242018	1	General, Exposure	2.6.1	Perchloroethylene is essential for cleaning mission-critical, high-value military flight hardware. The process is non-emissive (under one tenth of a pound lost to the air per year), with negligible worker exposure. Details were submitted to this docket as comment EPA-HQ-OPPT-2016-0732-0014 and are reported again to be responsive to the current EPA request for comments.	N	N	N	Y	N	N	N	N	N	N	N
283	ACOEMCommentAugust82018	1	General	N/A	The American College of Occupational and Environmental Medicine (ACOEM) is pleased to respond to the EPA's request for comments about its planned chemical evaluation for trichloroethylene (TCE). EPA is requesting any information from the public on trichloroethylene (TCE), both domestically and internationally. ACOEM represents more than 4,000 physicians and other health care professionals specializing in the field of occupational and environmental medicine (OEM). Founded in 1916, ACOEM is the nation's largest medical society dedicated to promoting the health of workers through preventive medicine, clinical care, research, and education. A dynamic group of physicians encompassing specialists in a variety of medical practices is united via the College to develop positions and policies on vital issues relevant to the practice of preventive medicine both within and outside of the workplace.	Y	N	N	N	N	N	N	N	N	N	N
284	ACOEMCommentAugust82018	1	Exposure, PESS	2.3.5	We recognize that the literature on the health effects of exposure to trichloroethylene (TCE) is extensive. Additionally, ACOEM recognizes that occupationally exposed workers represent a particular susceptible subpopulation, deserving of special scrutiny.	N	N	N	N	N	N	N	N	N	Y	N
285	ACOEMCommentAugust82018	1	RegNex, Human Health, Exposure	N/A	OSHA's current permissible exposure limit (PEL) for TCE (100 ppm for Federal OSHA, or 537 mg/cu m, as an 8-hour time-weighted average), would theoretically permit a worker to be exposed to as much as 2,500 mg of trichloroethylene per day, assuming a breathing rate of 10 cu meters per 8-hour shift and an absorption factor exceeding 50%. Exposures in this range over a lifetime would impose an incremental lifetime cancer risk for exposed workers markedly exceeding 1 chance in 100, taking account of the current cancer potency estimates for TCE. Such exposures are also strongly suspected to be associated with an increased risk for reproductive toxicity. ACOEM applauds EPA's previous recognition of these increased reproductive risks particularly in occupationally exposed populations. OSHA's current permissible exposure limit (PEL) for TCE (100 ppm for Federal OSHA, or 537 mg/cu m, as an 8-hour time-weighted average), would theoretically permit a worker to be exposed to as much as 2,500 mg of trichloroethylene per day, assuming a breathing rate of 10 cu meters per 8-hour shift and an absorption factor exceeding 50%. Exposures in this range over a lifetime would impose an incremental lifetime cancer risk for exposed workers markedly exceeding 1 chance in 100, taking account of the current cancer potency estimates for TCE. Such exposures are also strongly suspected to be associated with an increased risk for reproductive toxicity. ACOEM applauds EPA's previous recognition of these increased reproductive risks particularly in occupationally exposed populations.	N	N	N	N	N	N	N	N	N	Y	N
286	ACOEMCommentAugust82018	1	Fate	2.3, 2.6.1	In addition, ACOEM is concerned about the fate of TCE released into the environment, whether in the form of surface-run off, release from storage tanks, or other unintended releases. The extent of persistent groundwater contamination with TCE has been documented in many parts of the nation.	N	N	N	N	N	N	N	N	N	Y	N
287	ACOEMCommentAugust82018	1	Exposure	2.3.5, 2.6.1	We urge EPA to consider all sources of exposure to trichloroethylene in potentially exposed workers, to assure that cumulative exposures from occupational uses, from ambient air, and/or from drinking water do not exceed an acceptable level.	N	N	N	N	N	N	N	N	N	Y	N
288	ACOEMCommentAugust82018	1	Human Health, Exposure	2.3.5, 2.6.1	Accordingly, ACOEM urges EPA to consider both the cancer and non-cancer health effects resulting from exposure to TCE, particularly in occupationally exposed populations, where exposure is likely to be highest.	N	N	N	N	N	N	N	N	N	Y	N
289	ACOEMCommentAugust82018	1	Fate	2.3., 2.6.1	Furthermore, given the long record of TCE environmental contamination, particularly involving groundwater, ACOEM encourages EPA to include in its chemical evaluation the environmental fate and environmental impacts of TCE use, both from intended uses, as well as from uses that may be unintended but are reasonably foreseeable.	N	N	N	N	N	N	N	N	N	Y	N
290	ACOEMCommentAugust82018	1	General	N/A	Furthermore, ACOEM would see great merit in sharply restricting the use of TCE for degreasing operations.	N	N	N	N	N	N	N	N	N	Y	N
291	HSIACommentJune62018	1	General	N/A	The Halogenated Solvents Industry Alliance, Inc. (HSIA) is pleased to have the opportunity to offer these comments on EPA's proposed rule to strengthen transparency in regulatory science. 83 Fed. Reg. 18768 (April 30, 2018). The intent of this rule is to ensure that EPA uses scientific information in its assessments that is publicly available to allow for independent validation, particularly when the scientific studies are pivotal to regulatory action. HSIA represents producers and users of trichloroethylene (TCE), and HSIA's experience with assessments ofthat chemical by two EPA program offices has highlighted the need for greater transparency in that process.	N	N	N	N	N	N	N	N	N	Y	N
292	HSIACommentJune62018	1	Human Health	N/A	In 2011 , EPA derived a reference concentration (RfC) of 0.0004 ppm (0.4 ppb or 2)ug/m3) and a reference dose (RfD) of 0.0005 mg/kg-day for TCE. EPA's derivation of the RfC/RfD for TCE was based, in part, on Johnson et al., Threshold of Trichloroethylene Contamination in Maternal Drinking Waters Affecting Fetal Heart Development in the Rat, Environ. Health Perspect. 111: 289-92 (2003). This assessment was subsequently adopted in the TSCA Chemicals Work Plan Assessment for TCE.	N	N	N	N	N	N	N	N	N	Y	N

293	HSIACommentJune6 2018	1	Human Health	N/A	As noted in the proposed rule, both transparency and independent validation of key findings of a study (reproducibility) are necessary in EPA's scientific assessments to ensure "that the quality of published infonnation meets the standards of the scientific and technical community." For reasons discussed below, the Johnson et al. (2003) study meets neither of these standards and should not be used to develop toxicological values that serve as the basis for regulation.	N	N	N	N	N	N	N	N	N	Y	N
294	HSIACommentJune6 2018	1	Other/Human Health	N/A	1. Data records for Johnson et al. (2003) are inadequate or non-existent HSIA's attempts to see the raw data which formed the basis of the Johnson et al. (2003) study report have been unsuccessful. When HSIA requested access to the data used by EPA in its evaluation of the dose-response relationship between TCE exposure and cardiac defects reported in Johnson et al. (2003), the Agency provided the spreadsheet, referenced as Johnson (2009) (HERO ID 783484) in the 2011 IRIS Assessment, and indicated that was the entirety of the data evaluated. Examination of that spreadsheet reveals an absence of certain critical information, including most importantly dates for any of the individual treatment/control animals. Acknowledging the documented deficiencies in their paper (and the data provided to EPA), the authors published an erratum aimed at updating the public record regarding methodological issues for Johnson et al. (2003).	N	N	N	N	N	N	N	N	N	Y	N
295	HSIACommentJune6 2018	1	Human Health	N/A	According to Makris et al. (2016): "some study reporting and methodological details remain unknown, e.g., the precise dates that each individual control animal was on study, maternal body weight/food consumption and clinical observation data, and the detailed results of analytical chemistry testing for dose concentration. Additional possible sources of uncertainty identified for these studies include that the research was conducted over a 6-year period, that combined control data were used for comparison to treated groups, and that exposure characterization may be imprecise because tap (rather than distilled) drinking water was used in the Dawson et al. (1993) study and because TCE intake values were derived from water consumption measures of group-housed animals." HSIA submits that the information contained in the above paragraph alone constitutes a transparency as well as a data quality concern sufficient to preclude Johnson et al. (2003) from being used as the basis for regulation. A direct appeal to Dr. Johnson failed to make the data available for public scrutiny. And a Freedom of Information Act request pursuant to the Shelby Amendment was denied by the National Institutes of Health.	N	N	N	N	N	N	N	N	N	Y	N
296	HSIACommentJune6 2018	1	Human Health	N/A	The transparency problem with Johnson et al. (2003) was pointed out by the peer review of the TSCA Chemicals Work Plan assessment for TCE. An excerpt from the peer review report is reproduced below: "Unfortunately, Johnson et al (2003) failed to report the source or age of their animals, their husbandry or provide comprehensive historical control data for spontaneous cardiovascular malformations in their colony. The Johnson study with 55 control litters compared to 4 affected litters of 9 treated was apparently conducted over a prolonged period of time (perhaps years); it is possible this was due to the time required to dissect and inspect fresh rodent fetuses by a small academic group. However, rodent background rates for malformations, anomalies and variants show temporal fluctuations (WHO, 1984) and it is not clear whether the changes reported by Johnson et al. (2005) were due to those fluctuations or to other factors. Surveys of spontaneous rates of terata in rats and other laboratory animals are common particularly in pharmaceutical and contract laboratory safety assessments (e.g., Fritz et al., 1978; Grauwiler, 1969; Palmer, 1972; Perraud, 1976). The World Health Organization (1984) advised: "'Control values should be collected and permanently recorded. They provide qualitative assurance of the nature of spontaneous malformations that occur in control populations. Such records also monitor the ability of the investigator to detect various subtle structural changes that occur in a variety of organ systems.' "Rates of spontaneous congenital defects in rodents can vary with temperature and housing conditions. For example, depending on the laboratory levocardia and cardiac hypertrophy occur in rats at background rates between 0.8-1.25% (Perraud, 1976). Laboratory conditions can also influence study outcome; for instance, maternal hyperthermia (as a result of ambient elevated temperature or infection) can induce congenital defects (including cardiovascular malformations) in rodents and it acts synergistically with other agents (Aoyama et al., 2002; Edwards, 1986; Zinskin and Morrissey, 2011). Thus while the anatomical observations made by Johnson et al. (2003) may be accurate, in the absence of data on maternal well-being (including body weight gain), study details (including investigator blind investigations), laboratory conditions, positive controls and historical rates of cardiac terata in the colony it is not possible to discern the differences between the Johnson et al. (2003) results and those of other groups. As noted by previous investigators, the rat fetus is 'clearly at risk both to parent TCE and its TCE metabolite' given sufficiently high prenatal TCE exposures that can induce neurobehavioral deficits (Fisher et al, 1999; Taylor et al., 1985), but no focus on cardicac terata limited to studies in one laboratory that have not been reproduced in other (higher dose) studies and apply the BMD01 with additional default toxicodynamic uncertainty factors appears misleading."	N	N	N	N	N	N	N	N	N	Y	N
297	HSIACommentJune6 2018	1	Human Health	N/A	HSIA had consistently maintained that the data presented in Johnson et al. (2003) and subsequently clarified in the two errata do not allow calculations of the incidence of cardiac malformations per litter that is time-matched to concurrent controls (the standard practice for evaluation of developmental toxicity studies). Accepting the authors' claim in the 2014 erratum that exposure times cannot be confirmed for substantial amounts of either control or treatment data, it also can be presumed that it is now impossible to reconstruct a calculation of per litter incidence of cardiac malformations that is appropriately matched to concurrent controls. Thus, the data reported in Johnson et al. (2003), even as amended in two subsequent errata, do not allow for data analysis generally accepted as essential to interpreting outcomes of developmental toxicity study findings. The lack of data availability and clarity sufficient to construct key analyses associated with a key study should disqualify the use of that study in important decisions such as RfC/RfD derivations used for regulatory purposes.	N	N	N	N	N	N	N	N	N	Y	N
298	HSIACommentJune6 2018	1	Human Health	N/A	2. Johnson et al. (2003) is not reproducible At least two GLP-compliant studies (Carney et al. 2006; Fisher et al. 2001) conducted under both EPA and Organization for Economic Coordination and Development (OECD) guidelines have been unable to reproduce the effect seen by Johnson et al. (2003), despite the participation in one of the studies by Johnson herself. Significant to the proposed transparency rule, Carney et al. (2006) was conducted as part of a voluntary testing program between the HSIA and the Agency for Toxic Substances & Disease Registry (ATSDR). All stages of the testing, from development of the protocol to the final report, underwent extensive peer review by scientists from three separate governmental agencies (ASTDR, EPA, and the National Toxicology Program), as well as external experts. In addition, the protocol and study report (which includes the raw data) are available to the public. Carney et al. (2006) meets the highest standard of transparency that can be achieved for EPA's assessment needs.	N	N	N	N	N	N	N	N	N	Y	N
299	HSIACommentJune6 2018	1	Human Health	N/A	A third guideline study of TCE developmental toxicity is now being sponsored by HSIA, with results expected by September 2018. The study is designed with a focus on cardiac abnormalities and includes toxicokinetic measures to enable comparison with the earlier studies. It is intended to fill the remaining gap for a guideline study by the drinking water route, the same exposure route as Johnson et al. (2003). Keeping TCE in the drinking water solutions and achieving acceptable target concentrations of TCE in the drinking water has been challenging because of the high propensity of TCE to volatilize into the air. For this reason, the concentrations of TCE in the drinking water formulations will be sampled prior to transfer into the rat drinking water bottles at multiple times during the study, including time points that bracket the period of fetal heart development. The study will also include a determination on how much TCE is lost from the dosing solutions in the water bottles when placed in the animal cages over the course of a 24-hour exposure period. All data will be made publicly available in the study report.	N	N	N	N	N	N	N	N	N	Y	N

300	HSIACommentJune6 2018	1	Human Health/Exposure	N/A	In summary, we support EPA's proposed transparency rule and point to the use of Johnson et al. (2003) in EPA's derivation of toxicological values for TCE as an example of why the rule is needed. There has been a great deal of public concern regarding cardiac malformations from exposure to TCE in indoor air as a consequence of EPA's derivation of the IRIS RfC/RfD for TCE using the Johnson et al. (2003) study. In 2014, EPA Region 9 issued action levels of 8 ug/m3 (commercial and industrial) for an 8-hour workday and 2 ug/m3 (residential) for short-term exposures to TCE at Superfund sites under its jurisdiction. The short-term exposure limit of 2 ug/m3 is based on the IRIS RfC/RfD for TCE and was intended by Region 9 "to be protective of sensitive and vulnerable populations, especially women in the first trimester of pregnancy, because of the potential for cardiac malformations to the developing fetus."	N	N	N	N	N	N	N	N	N	Y	N
301	HSIACommentJune6 2018	1	Human Health, Exposure	N/A	Mitigation measures to achieve this short-term exposure limit include evacuation of residents or workers from buildings. Regions 9's short-term exposure limit is now being adopted by states to protect against the risk of cardiac malformations from TCE exposure in indoor air from contaminated sites, even though the more relevant route of exposure for this regulatory action by federal and state agencies is by inhalation of TCE vapor and not orally from drinking water. The only animal developmental study conducted on TCE by the inhalation route (Carney et al. 2006) showed no indication of developmental toxicity, including cardiac malformations.	N	N	N	N	N	N	N	N	N	Y	N
302	HSIACommentAugust22018	2	Human Health	N/A	The Halogenated Solvents Industry Alliance, Inc. (HSIA) represents producers and users of trichloroethylene. We are submitting the protocol of the on-going HSIA-sponsored study titled "An Oral (Drinking Water) Study of the Effects of Trichloroethylene (TCE) on Fetal Heart Development in Sprague Dawley Rats." The purpose of this study is to replicate the findings of Johnson et al., Threshold of Trichloroethylene Contamination in Maternal Drinking Waters Affecting Fetal Heart Development in the Rat, Environ. Health Perspect. 111: 289-292 (2003).	N	N	N	N	N	N	N	N	N	Y	N
303	OhioUnivCommentAugust82018	1	Exposure	N/A	[Letter addressed to Dr. Croyle of the National Cancer Institute (NCI] It was a pleasure to meet you in Washington, DC at the meeting of the State Leadership Council of the National Rural Health Association on July 18th. Thank you for coming to this meeting and for explaining NCI's emphasis on understanding cancers in rural areas. As we briefly discussed, I have been working with colleagues to explore possible reasons for prostate cancer cases among men who were security guards at a uranium enrichment facility in rural, Appalachia Ohio. These men were diagnosed prior to the age of 60 with aggressive prostate cancer and it seems as if this is more common than expected. The information below summarizes the situation and includes a background of the facility for orientation purposes. I also include a synopsis of some of the work we have done, potential research questions and activities, and a request for support from NCI.	N	N	N	N	N	N	N	N	N	Y	N
304	OhioUnivCommentAugust82018	1	Exposure	N/A	[Detailed descriptions of the following were provided: Background of the Portsmouth Gaseous Diffusion Plant ("PORTS"; a uranium enrichment plant in Ohio built in the 1950s), the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), background of former workers (specifically security guards), the relationship between prostate cancer and TCE exposure, and a pilot project conducted by ARHI.] [Pilot Project:] Faculty in the Appalachian Rural Health Institute (ARHI), the Environmental Health Science program, and the Department of Geography have been exploring the cases of prostate cancer at PORT. This pilot research has included: 1. Interviews and a focus group with former employees; 2. A class case-study project, involving former workers and U.S. EPA; and 3. Interviews with men who did not work at the plant. [description of interview and focus groups]	N	N	N	N	N	N	N	N	N	Y	N
305	OhioUnivCommentAugust82018	1	Exposure	N/A	Class Project: Seniors at Ohio University in an Environmental Health and Safety Risk Assessment class conducted a case study of TCE. They ultimately made recommendations about whether it was "as least as likely as not" that there is a relationship between TCE and prostate cancer. As part of the case study, students heard presentations from former security guards and spoke with the U.S. EPA contact for the current risk evaluation for TCE. The risk evaluation was initiated in December of 2016 and the scope of the risk evaluation was published in June of 2017. The consensus of the students in this class was that there is a reason to further evaluate the relationship between TCE exposure and prostate cancer.	N	N	N	N	N	N	N	N	N	Y	N
306	OhioUnivCommentAugust82018	1	Human Health	2.4	On June 11, 2018, US EPA opened a public comment period on the Problem Formulation of the Risk Evaluation for Trichloroethylene. On July 24, 2018, the public comment period was extended until August 16, 2018. Although the problem formulation document is not final, it does state that EPA expects that inhalation is likely to be the most important exposure pathway for workers who did not directly work with TCE. Health effects from direct inhalation exposure to TCE include throat irritation and heart arrhythmias. Health effects from inhalation episodes can be compounded in areas with high temperatures. This is because phosgene can form when chlorinated hydrocarbons (TCE included) are exposed to high temperatures. Phosgene is a poisonous gas and health effects from acute exposure include coughing, burning sensation in the throat and eyes, difficulty breathing, and nausea and vomiting. Like TCE, phosgene has been found all over the PORTS site and the SEM notes one documented incident of trichloroethylene and phosgene exposure in 1980 at PORTS.	N	N	N	N	N	N	N	N	N	Y	N
307	OhioUnivCommentAugust82018	1	Human Health	2.4	[description of interviews] Although we are still analyzing the interview data, we have identified the following: 1) All the former PORTS security guards we interviewed (cases and controls) experienced at least one acute chemical exposure when responding to an incident at the site. 2) All the men we interviewed, except for control #4, believed they had been exposed to dangerous chemicals in their workplaces. 3) All the former PORTS security guards we interviewed, regardless of tenure and health status, believed that they were exposed to chemicals and radiation and these exposures were preventable if they had been provided with PPE. 4) None of the former plant workers had any knowledge of being exposed to TCE. However, the men who are being compensated for bilateral sensorineural hearing loss fall under Part E specifically from exposure to TCE.	N	N	N	N	N	N	N	N	N	Y	N
308	OhioUnivCommentAugust82018	1	Exposure	N/A	Request for Support and Research Question. For almost two years we have been exploring the unusual cases of aggressive prostate cancer diagnosed in former security guards from PORTS at younger age than expected. During this work we have spoken to former workers at the plant, examined published research, talked with health officials, involved students, and interviewed men who did not work at the plant. We started this exploration looking for a possible connection between prostate cancer and radiation exposure, but this research question has evolved to address a possible association between TCE exposure and prostate cancer. A summary of our findings: 1) Some former security guards at PORTS have been diagnosed with aggressive prostate cancer at an earlier age than expected. 2) Some of the former security guards at PORTS who have been diagnosed with prostate cancer are currently receiving compensation for BSHL under Part E because of exposure to TCE. 3) Clean-up activities have identified TCE as one of the most common contaminants in groundwater at the site. 4) The site exposure matrix for PORTS identifies more than 80 chemicals that security guards could have been exposed to including TCE and phosgene. 5) Some previous research suggests an association between TCE and prostate cancer, but more research is needed.	N	N	N	N	N	N	N	N	N	Y	N

309	OhioUnivCommentAugust82018	1	Exposure	N/A	These preliminary findings lead us to the overarching research question: Is there an association between exposure to TCE and prostate cancer? To answer this question, we are requesting that NCI consider supporting a large case-control epidemiologic study that will greatly expand the work we have done in this pilot. The case definition would need to be expanded and refined. We would gather qualitative data through interviews and quantitative data through surveys. While there are limitations to this type of observational epidemiology, it could contribute to additional understanding about the likelihood of developing prostate cancer from environmental and occupational exposures. Furthermore, this case clearly addresses NCI's emphasis on understanding cancer in rural areas.	N	N	N	N	N	N	N	N	N	Y	N
310	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	General	N/A	The Halogenated Solvents Industry Alliance, Inc. (HSIA) represents producers and users of trichloroethylene. We offer these comments on EPA's problem formulation for the risk evaluation of trichloroethylene under the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act enacted in June 2016. 83 Fed. Reg. 26998 (June 11, 2018). HSIA agrees with the condition of use proposed in the problem formulation document as being appropriate for the risk evaluation and is pleased that EPA is implementing systematic review approaches in all aspects of the risk evaluation.	N	N	N	N	N	N	N	N	N	Y	N
311	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	RegNex	N/A	HSIA further agrees with EPA that legacy sources of exposure should be excluded from the risk evaluation of trichloroethylene. Legacy sources of exposure typically refer to historical releases of a chemical to the environment associated with misuse or disposal. Although legacy environmental sources of exposure certainly exist for trichloroethylene, they have been managed for decades under various federal programs (i.e., CERCLA, RCRA, CAA, etc.). Many states also have stringent programs for addressing legacy contamination from these chemicals. Management of legacy contamination through the various federal and state programs is already risk-based and adding an additional risk-management program to the existing mix would be duplicative and not needed	N	N	N	N	N	N	N	N	N	Y	N
312	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	General	N/A	I. Requirements of TSCA §§ 6 and 26 TSCA § 6(b)(4)(F), as revised by the Lautenberg Act, requires that EPA's risk evaluations must, among other things: • "integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator;" • "take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance;" and • "describe the weight of the scientific evidence for the identified hazard and exposure."	N	N	N	N	N	N	N	N	N	Y	N
313	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	General	N/A	New TSCA § 26(h) requires that, in carrying out § 6, "to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science, and shall consider as applicable— (1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information; (2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture; (3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented; (4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and (5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models." Further, new TSCA § 26(i) provides: "The Administrator shall make decisions under sections 4, 5, and 6 based on the weight of the scientific evidence."	N	N	N	N	N	N	N	N	N	Y	N
314	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Exposure	2.2.2.2	The problem formulation for the risk evaluation of TCE includes degreasing and spot cleaning uses, which HSIA strongly supports. These two uses had been evaluated in 2014 in EPA's TSCA Work Plan Assessment for TCE, but the evaluation procedure was deficient as it did not comply with the "best available science" and "weight of scientific evidence" requirements under TSCA §§ 6 and 26. As the Chair noted in the peer review of the draft TSCA Work Plan Assessment: "The principal criterion for inclusion/exclusion [in the Work Plan assessment] would be the credibility/integrity of the study rather than simply the route of exposure. . . . If the Agency had conducted a systematic review of the literature and each study as it was developing the IRIS document, it would be a relatively easy task to identify the one best data set to represent the endpoint/duration of exposure /(sub)population to be evaluated. But there is not documentation to show that this exercise was carried out. . . . If [OPPT] didn't do its own systematic review of those . . . studies before using them, in the screening level assessment, it should do it before keeping them in a refined assessment."	N	N	N	N	N	N	N	N	N	Y	N
315	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	N/A	II Non-Cancer Assessment. A. Re-assessment of cardiac malformations from Johnson et al (2003) study. EPA's derivation of the current inhalation reference concentration (RfC) and oral reference dose (RfD) for TCE in its IRIS database is based, in part, on Johnson et al., Threshold of Trichloroethylene Contamination in Maternal Drinking Waters Affecting Fetal Heart Development in the Rat, Environ. Health Perspect. 111: 289-92 (2003). At least two GLP-compliant studies (Carney et al. 2006; Fisher et al. 2001) conducted under both EPA and Organization for Economic Coordination and Development (OECD) guidelines have been unable to reproduce the effect seen by Johnson et al. (2003).	N	N	N	N	N	N	N	N	N	Y	N
316	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	N/A	A third guideline study of TCE developmental toxicity sponsored by HSIA is underway, and the results are expected by the end of October 2018. The study is designed with a focus on cardiac abnormalities and includes toxicokinetic measures to enable comparison with the earlier studies. It is intended to fill the remaining gap for a guideline study by the drinking water route, the same exposure route as Johnson et al. (2003). Keeping TCE in the drinking water solutions and achieving acceptable target concentrations of TCE in the drinking water has been challenging because of the high propensity of TCE to volatilize into the air, as illustrated below in Table 1 [p. 4 of comments] Table 1 lists the vapor pressure, water solubility, and Henry's Law constant for TCE and several other volatile chemicals that have been tested in drinking water toxicity studies.	N	N	N	N	N	N	N	N	N	Y	N

317	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health, Fate	N/A	The Henry's Law constant is the equilibrium distribution of a chemical between the concentration in air and the concentration in water; it is commonly derived simply as the ratio of vapor pressure and solubility. A comparison of the Henry's Law constants for the volatile chemicals in Table 1 shows that TCE has a far greater tendency to transfer to air than the other volatile chemicals. While there were no reported problems of volatility loss of chloroform, EDC, MTBE, or acetone from the drinking water formulations in animal toxicity studies, this was found to be problematic in the earlier drinking water study sponsored at the same laboratory by HSIA. In this study, there was a significant problem with TCE volatility loss during the preparation of the dosing formulations and in the transfer of these formulations to the drinking water bottles; it was particularly severe at the lower concentrations (0.25 and 1.5 ppm TCE). Johnson et al. (2003) reported a 34% loss of TCE from the drinking water bottles over the 24-hour period in the animal cages, but the laboratory provided almost no information on the method used to minimize TCE loss during the preparation step of the dosing formulations, the concentrations of TCE achieved in the drinking water bottles at the start of each exposure period, and the variability of these concentrations throughout the study. This lack of reporting detail and analytical chemistry testing data for dose concentrations has been identified as one of the many deficiencies of the Johnson et al. (2003) study (Makris et al., 2016; Wikoff et al., 2018).	N	N	N	N	N	N	N	N	N	Y	N
318	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health, Fate	N/A	For the re-run of the HSIA-sponsored TCE developmental toxicity study, a method has been developed by the testing facility that allows the target concentrations to be met within a reasonable range. The method involves preparing the dosing formulations on a daily basis and in a closed system; headspace is minimized. For the transfer of the dosing formulations into the water bottles, nitrogen is pumped into the inlet valve of the dosing formulation vessel, displacing the dosing formulation through the outlet value and into the drinking water bottle. A feasibility study was recently conducted to ensure that the dosing formulations could be prepared consistently on a daily basis and to quantitate how much TCE loss would occur from the drinking water bottles over the 24-hour period in the animal cages. Pregnant female SD Crl:CD(SD) rats were given in their drinking water 0.25 or 1,000 ppm TCE from gestation days (GD) 11 to 13. The dosing formulations were given to the rats at the same time of the day (within 2-3 hours) on GD 11 and 12. For the 1,000 ppm TCE dose group, the concentrations of TCE in the prepared dosing formulations for the two test days were 97% and 105% of the target concentration, and 102% and 103% after being added to the water bottles. For the 0.25 ppm TCE dose group, the concentrations of TCE in the dosing formulations for the two days were 136% and 123% of the target concentrations, and 132% and 132% after being added to the water bottles. The losses of TCE from the water bottles over the 24-hour period were 34% and 31% for the 0.25 and 1,000 ppm dosing groups, respectively. While the TCE losses from the water bottles over the 24-hour exposure period are unavoidable, these results show that the method developed by the testing facility for the HSIA-sponsored developmental study achieves minimal TCE volatility loss, resulting in consistent daily TCE drinking water concentration.	N	N	N	N	N	N	N	N	N	Y	N
319	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	N/A	B. Critiques of Johnson et al. (2003) in literature and by other regulators. Johnson et al. (2003) reported cardiac effects in rats from research carried out at the University of Arizona and originally published ten years earlier by the same authors.7 In the earlier-published study, there was no difference in the percentage of cardiac abnormalities in rats dosed during both pre-mating and pregnancy at drinking water exposures of 1100 ppm (9.2%) and 1.5 ppm (8.2%), even though there was a 733-fold difference in the concentrations. The authors reported that the effects seen at these exposures were statistically higher than the percent abnormalities in controls (3%). For animals dosed only during the pregnancy period, the abnormalities in rats dosed at 1100 ppm (10.4%) were statistically higher than at 1.5 ppm (5.5%), but those dosed at 1.5 ppm were not statistically different from the controls. Thus, no meaningful dose-response relationship was observed in either treatment group. Johnson et al. republished in 2003 data from the 1.5 and 1100 ppm dose groups published by Dawson et al. in 1993 and pooled control data from other studies, an inappropriate statistical practice, to conclude that rats exposed to levels of TCE greater than 250 ppb during pregnancy have increased incidences of cardiac malformations in their fetuses.	N	N	N	N	N	N	N	N	N	Y	N
320	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	N/A	Johnson et al. (2003) has been heavily criticized in the published literature. Indeed, its predecessor study was expressly rejected as the basis for MRLs by the Agency for Toxic Substances & Disease Registry (ATSDR) in its last TCE Toxicological Profile Update. Moreover, as noted above, the Johnson et al. (2003) findings were not reproduced in a study designed to detect cardiac malformations; this despite employing an improved method for assessing cardiac defects and the participation of Dr. Johnson herself. No increase in cardiac malformations was observed in the second guideline study, despite high inhalation doses and techniques capable of detecting most of the malformation types reported by Johnson et al. (2003). The dose-response relationship reported in Johnson et al. (2003) for doses spanning an extreme range of experimental dose levels is considered by many to be improbable, and has not been replicated by any other laboratory.	N	N	N	N	N	N	N	N	N	Y	N
321	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	N/A	Even the California Office of Environmental Health Hazard Assessment (OEHHA) rejected the study as deficient: "Johnson et al. (2003) reported a dose-related increased incidence of abnormal hearts in offspring of Sprague Dawley rats treated during pregnancy with 0, 2.5 ppb, 250 ppb, 1.5 ppm, and 1,100 ppm TCE in drinking water (0, 0.00045, 0.048, 0.218, and 128.52 mg/kg-day, respectively). The NOAEL for the Johnson study was reported to be 2.5 ppb (0.00045 mg/kg-day) in this short exposure (22 days) study. The percentage of abnormal hearts in the control group was 2.2 percent, and in the treated groups was 0 percent (low dose), 4.5 percent (mid dose 1), 5.0 percent (mid dose 2), and 10.5 percent (high dose). The number of litters with fetuses with abnormal hearts was 16.4 percent, 0 percent, 44 percent, 38 percent, and 67 percent for the control, low, mid 1, mid 2, and high dose, respectively. The reported NOAEL is separated by 100-fold from the next higher dose level. The data for this study were not used to calculate a public-health protective concentration since a meaningful or interpretable dose-response relationship was not observed. These results are also not consistent with earlier developmental and reproductive toxicological studies done outside this lab in mice, rats, and rabbits: The other studies did not find adverse effects on fertility or embryonic development, aside from those associated with maternal toxicity (Hardin et al., 2004)."	N	N	N	N	N	N	N	N	N	Y	N
322	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	N/A	C. Reservations by EPA scientific staff. Remarkably, an EPA staff review that was placed in the docket for the earlier Work Plan Assessment reflects similar concerns. First, one staff member dissented over relying at all on the Arizona study: "The rodent developmental toxicology studies conducted by Dawson et al. (1993), Johnson et al. (2003), and Johnson et al. (1998) that have reported cardiac defects resulting from TCE (and metabolite) drinking water exposures have study design and reporting limitations. Additionally, two good quality (GLP) inhalation and gavage rodent studies conducted in other laboratories, Carney et al. (2006) and Fisher et al. (2001), respectively, have not detected cardiac defects. These limitations and uncertainties were the basis of the single dissenting opinion of a team member regarding whether the database supports a conclusion that TCE exposures during development are likely to cause cardiac defects."	N	N	N	N	N	N	N	N	N	Y	N
323	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	N/A	Second, even the EPA staff that agreed with use of the study had little confidence that it supported the dose-response assessment: "[A] majority of the team members agreed that the Johnson et al. (2003) study was suitable for use in deriving a point of departure. However, confidence of team members in the dose response evaluation of the cardiac defect data from the Johnson et al. (2003) study was characterized as between 'low' and 'medium' (with 7 of 11 team members rating confidence as 'low' and four team members rating confidence as 'low to medium'). The same report notes: "In conclusion, there has not been a confirmation of the results of the Johnson et al. (2003) and Dawson et al. (1993) studies by another laboratory, but there has also not been a repeat of the exact same study design that would corroborate or refute their findings."	N	N	N	N	N	N	N	N	N	Y	N

324	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	N/A	D. EPA's dose-response analysis of Johnson et al. (2003) data needs to be re-examined. The IRIS assessment's evaluation of the relationship between TCE exposure dose and the development of cardiac defects relies heavily on Johnson et al. (2003). Ignoring for the moment the methodological deficiencies in the paper, a closer look at EPA's evaluation of that dose-response relationship in generating a point of departure (POD) raises several concerns. This is important, as according to a paper published by the authors of the IRIS Assessment, Johnson et al. (2003) represents "the only available study potentially useable for dose-response analysis of fetal cardiac defects."	N	N	N	N	N		N	N	N	N	Y	N
325	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	N/A	In discussing the dose-response evaluation, Makris et al. (2016) further state that "[g]iven the uncertainties in the dose-response analysis related to the nature of the data, the confidence in the POD based on Johnson et al. (2003) has limitations. Overall, however, the POD derived in the 2011 TCE assessment (U.S. EPA, 2011), which used an approach consistent with standard U.S. EPA dose-response practices, remains a reasonable choice." It should be noted that, in order to achieve a better model fit in its derivation of a POD, EPA dropped the highest exposure dose from Johnson et al. (2003). With already questionable data, and no expectation that the highest dose of TCE would result in a diminished response, that decision should be reconsidered. Makris et al. (2016) describe additional dose-response analyses performed to characterize the uncertainty in the POD. In summarizing the results of this analysis, they state that "[a]lternative PODs were derived based on use of alternative models, alternative BMR levels, or alternative procedures (such as LOAEL/NOAEL approach), each with different strengths and limitations. These alternatives were within about an order of magnitude of the POD derived in the 2011 TCE assessment" (emphasis added). This level of uncertainty in modeling the POD when combined with the uncertainty in the PBPK modeling (discussed elsewhere) and the overall poor quality of the underlying developmental toxicity study provide little confidence in this toxicological value.	N	N	N	N	N		N	N	N	N	Y	N
326	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	N/A	E. Reliance of Johnson et al. (2003) is inconsistent with use of best available science. When HSIA requested access to the data used by EPA in its evaluation of the dose-response relationship between TCE exposure and cardiac defects reported in Johnson et al. (2003), the Agency provided the spreadsheet, referenced as Johnson (2009) (HERO ID 783484) in the 2011 IRIS Assessment, and indicated that was the entirety of the data evaluated. Examination of that spreadsheet reveals an absence of certain critical information, including, most importantly, dates for any of the individual treatment/control animals.	N	N	N	N	N		N	N	N	N	Y	N
327	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	N/A	Acknowledging the documented deficiencies in their paper (and the data provided to EPA), the authors published an erratum aimed at updating the public record regarding methodological issues for Johnson et al. (2003). According to Makris et al. (2016): "some study reporting and methodological details remain unknown, e.g., the precise dates that each individual control animal was on study, maternal body weight/food consumption and clinical observation data, and the detailed results of analytical chemistry testing for dose concentration. Additional possible sources of uncertainty identified for these studies include that the research was conducted over a 6-yr period, that combined control data were used for comparison to treated groups, and that exposure characterization may be imprecise because tap (rather than distilled) drinking water was used in the Dawson et al. (1993) study and because TCE intake values were derived from water consumption measures of group-housed animals." HSIA submits that the information contained in the above paragraph alone should disqualify Johnson et al. (2003) as "best available science" as required under EPA's July 2017 procedures for chemical risk evaluation under TSCA as amended.	N	N	N	N	N		N	N	N	N	Y	N
328	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	N/A	III. Cancer Risk Assessment. A. Deficiencies of Cancer Risk Assessment. 1. Erroneous Characterization of TCE as "Carcinogenic to Humans": The IRIS Assessment classifies TCE as "Carcinogenic to Humans." It fails to discuss (or even to recognize) that such classification is inconsistent with a definitive report by the National Academy of Sciences, discussed below. First, we briefly address how the epidemiological data on TCE do not meet the threshold for classification as "Carcinogenic to Humans."	N	N	N	N	N		N	N	N	N	Y	N
329	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	N/A	a. Guidelines for Carcinogen Risk Asessment. EPA's 2005 Guidelines for Carcinogen Risk Assessment provide the following descriptors as to the weight of evidence for carcinogenicity: • Carcinogenic to humans, • Likely to be carcinogenic to humans, • Suggestive evidence of carcinogenicity, • Inadequate information to assess carcinogenic potential, and • Not likely to be carcinogenic to humans.	N	N	N	N	N		N	N	N	N	Y	N
330	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	N/A	According to the Guidelines, "carcinogenic to humans" means the following: "This descriptor indicates strong evidence of human carcinogenicity. It covers different combinations of evidence. • "This descriptor is appropriate when there is convincing epidemiologic evidence of a causal association between human exposure and cancer. •"Exceptionally, this descriptor may be equally appropriate with a lesser weight of epidemiologic evidence that is strengthened by other lines of evidence. It can be used when all of the following conditions are met: (a) There is strong evidence of an association between human exposure and either cancer or the key precursor events of the agent's mode of action but not enough for a causal association, and (b) there is extensive evidence of carcinogenicity in animals, and (c) the mode(s) of carcinogenic action and associated key precursor events have been identified in animals, and (d) there is strong evidence that the key precursor events that precede the cancer response in animals are anticipated to occur in humans and progress to tumors, based on available biological information. In this case, the narrative includes a summary of both the experimental and epidemiologic information on mode of action and also an indication of the relative weight that each source of information carries, e.g., based on human information, based on limited human and extensive animal experiments."	N	N	N	N	N		N	N	N	N	Y	N
331	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	N/A	According to the Guidelines, the descriptor "likely to be carcinogenic to humans": "is appropriate when the weight of the evidence is adequate to demonstrate carcinogenic potential to humans but does not reach the weight of evidence for the descriptor 'Carcinogenic to Humans.' Adequate evidence consistent with this descriptor covers a broad spectrum. . . . Supporting data for this descriptor may include: •"An agent demonstrating a plausible (but not definitively causal) association between human exposure and cancer; • "An agent that has tested positive in animal experiments in more than one species, sex, strain, site or exposure route, with or without evidence of carcinogenicity in humans; •"A positive tumor study that raises additional biological concerns beyond that of a statistically significant result, for example, a high degree of malignancy or an early age at onset; • "A rare animal tumor response in a single experiment that is assumed to be relevant to humans; or • "A positive tumor study that is strengthened by other lines of evidence."	N	N	N	N	N		N	N	N	N	Y	N

332	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	N/A	According to the Guidelines, the descriptor “suggestive evidence of carcinogenicity”: “is appropriate when the weight of evidence is suggestive of carcinogenicity; a concern for potential carcinogenic effects in humans is raised, but the data are judged not sufficient for a stronger conclusion. This descriptor covers a spectrum of evidence associated with varying levels of concern for carcinogenicity, ranging from a positive cancer result in the only study on an agent to a single positive cancer result in an extensive database that includes negative studies in other species. Depending on the extent of the database, additional studies may or may not provide further insights. Some examples include: •“A small, and possibly not statistically significant, increase in tumor incidence observed in a single animal or human study that does not reach the weight of evidence for the descriptor ‘Likely to Be Carcinogenic to Humans;’ •“A small increase in a tumor with a high background rate in that sex and strain, when there is some but insufficient evidence that the observed tumors may be due to intrinsic factors that cause background tumors and not due to the agent being assessed; • “Evidence of a positive response in a study whose power, design, or conduct limits the ability to draw a confident conclusion (but does not make the study fatally flawed), but where the carcinogenic potential is strengthened by other lines of evidence; or • “A statistically significant increase at one dose only, but no significant response at the other doses and no overall trend.”	N	N	N	N	N	N	N	N	N	Y	N
333	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	N/A	b. Application of the Guidelines to TCE. In considering the data in the context of applying the “Carcinogenic to Humans” descriptor, the weight of the epidemiological evidence must first be considered. We judge the epidemiologic evidence to be neither “convincing” nor “strong,” two key terms in the Guidelines. This judgment is based on four recent reviews and meta-analyses of occupational TCE exposures and cancer as well as other reviews of this literature.20 The recent review and meta-analysis by Kelsh et al. focuses on occupational TCE exposure and kidney cancer, and includes the Charbotel et al. study that is emphasized in the IRIS assessment.21 Both the EPA meta-analysis and the Kelsh et al. meta-analysis of the TCE kidney cancer epidemiologic literature produced similar summary results. However in Kelsh et al. the limitations of this body of research, namely exposure assessment limitations, potential unmeasured confounding, potential selection biases, and inconsistent findings across groups of studies, did not allow for a conclusion that there is sufficient evidence of a causal association, despite a modest overall association.	N	N	N	N	N	N	N	N	N	Y	N
334	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	N/A	There are reasonably well-designed and well-conducted epidemiologic studies that report no association between TCE and cancer, some reasonably well-designed and conducted studies that did report associations between TCE and cancer, and finally some relatively poorly designed studies reporting both positive and negative findings. Overall, the summary relative risks or odds ratios in the meta-analysis studies (EPA or published meta-analyses) generally ranged between 1.2 and 1.4. Such small odds ratios are not typically considered “convincing” or “strong.” Weak or small associations may be more likely to be influenced by or be the result of confounding or bias. Smoking and body mass index are well-established risk factors for kidney cancer, and smoking and alcohol are risk factors for liver cancer, yet the potential impact of these factors on the meta-analysis associations was not fully considered. There were suggestions that these factors may have impacted findings (e.g., in the large Danish cohort study of TCE exposed workers, the researchers noted that smoking was more prevalent among the TCE exposed populations, however little empirical data were provided). In addition, co-linearity of occupational exposures (i.e., TCE exposure correlated with chemical and/or other exposures) may make it difficult to isolate potential effects of TCE from those of other exposures within a given study, and hinder interpretation across studies. For example, although Charbotel et al. reported potential exposure response trends, while controlling for many confounders of concern (which strengthens the weight of evidence), they also reported attenuated associations for cumulative TCE exposure after adjustment for exposure to cutting fluids and other petroleum oils (weakening the weight of the evidence). This study is also limited due to other potential study design considerations such as selection bias, self reporting of work histories, and residual confounding.	N	N	N	N	N	N	N	N	N	Y	N
335	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	N/A	When examining the data for TCE and non-Hodgkin lymphoma, kidney cancer, and liver cancer, associations were inconsistent across occupational groups (summary results differed between aerospace/aircraft worker cohorts compared with workers from other industries), study design, location of the study, quality of exposure assessment (e.g., evaluating studies that relied upon biomonitoring to estimate exposure vs. semi-quantitative estimates vs. self-report, etc.), and by incidence vs. mortality endpoints. Although EPA examined high dose categories, it did not evaluate any potential dose-response relationships across the epidemiologic studies (except for Charbotel et al.). Reviews of the epidemiologic data reported in various studies for different exposure levels (e.g., cumulative exposure and duration of exposure metrics) did not find consistent dose-response associations between TCE and the three cancer sites under review. An established dose-response trend is one of the more important factors when making assessments of causation in epidemiologic literature. Thus, based on an overall weight of evidence analysis of the epidemiologic research, these data do not support the conclusion that there is “strong” or “convincing” evidence of a causal association between human exposure and cancer.	N	N	N	N	N	N	N	N	N	Y	N
336	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	N/A	EPA’s Guidelines also state that a chemical may be described as “Carcinogenic to Humans” with a lesser weight of epidemiologic evidence that is strengthened by other lines of evidence, all of which must be met. One of these lines of evidence is “extensive evidence of carcinogenicity in animals.” Therefore, we must briefly evaluate the animal data. The criteria that have to be met for animal data to support a “carcinogenic to humans” classification are stated in a sequential manner with an emphasized requirement that all criteria have to be met. Since the Guidelines consider this to be an “exceptional” route to a “carcinogenic to humans” classification, we would expect rigor to have been applied in assessing animal data against the criteria. This simply was not done.	N	N	N	N	N	N	N	N	N	Y	N
337	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	N/A	Of the four primary tissues that EPA evaluated for carcinogenicity, only one or perhaps two rise to the level of biological significance. Discussion of the remaining tumor types appears to presuppose that TCE is carcinogenic. The resulting discussion appears then to overly discount negative data, of which there are many, and to highlight marginal findings. The text does not appear to be a dispassionate rendering of the available data. Specifically, EPA’s conclusion that kidney cancer is evident in rats rests on one statistically significant finding in over 70 dose/tumor endpoint comparisons and references to exceedances of historical control values.23 Using a 0.05 p-value for statistical significance, a frequency of 1 or even several statistically or biologically significant events is expected in such a large number of dosed/tumor groups. EPA’s overall conclusion based on these flawed studies cannot be that TCE is a known kidney tumorigen. The best that can be said is that the data are inconsistent. Certainly they do not meet the criterion of “extensive evidence of carcinogenicity in animals.” Several marginal findings do not constitute “extensive evidence.” For all these reasons, EPA’s classification of TCE as “Carcinogenic to Humans” is not supported by the evidence and cannot be justified under the 2005 Guidelines. Footnote: 23 And that bioassay is from a laboratory whose studies EPA has reviewed and declined to rely upon in other assessments.	N	N	N	N	N	N	N	N	N	Y	N
338	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	2.4.2.2	c. EPA’s Position that there is ‘Convincing Evidence’ that TCE Is Carcinogenic to Humans is Inconsistent with National Academy of Sciences Conclusion of only ‘Limited or Suggestive Evidence’ The IRIS Assessment states that "TCE is characterized as ‘carcinogenic to humans’ by all routes of exposure. This conclusion is based on convincing evidence of a causal association between TCE exposure in humans and kidney cancer."	N	N	N	N	N	N	N	N	N	Y	N

339	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	2.4.2.2	Box 2 of the Academy's Camp Lejeune report, attached as Appendix 1, categorizes every cancer outcome reviewed in relation to exposure to TCE, the dry cleaning solvent perchloroethylene, or a mixture of the two. The categories are taken directly from a respected Institute of Medicine (IOM) report. These categories are "sufficient evidence of a causal relationship," "sufficient evidence of an association," "limited or suggestive evidence of an association," "inadequate evidence to determine an association," and "limited or suggestive evidence of no association," all as defined in Box 1, also attached. Looking at Box 2, evidence considered by EPA to be "convincing evidence of a causal association between TCE exposure in humans and kidney cancer" would seem to be considered "sufficient evidence of a causal relationship." Yet the Academy found no outcomes in that category. It would at least be "sufficient evidence of an association." Again, the Academy found no outcomes in that category. Only in the third category, "limited or suggestive evidence of an association," does one find kidney or any other cancer outcome associated with TCE.	N	N	N	N	N	N	N	N	N	Y	N
340	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	2.4.2.2	"Limited evidence of an association" is far from "convincing evidence of causation." One would expect at the least a detailed explanation of EPA's very different conclusion. Although the 2009 Camp Lejeune study was already published, and indeed is cited in the references, there is no mention of it in the text of the IRIS Assessment, even though the previous draft had just been the subject of a multi-year review by the Academy.	N	N	N	N	N	N	N	N	N	Y	N
341	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	2.4.2.2	The Camp Lejeune committee began with a comprehensive review of the epidemiology studies of the two solvents by the IOM for its Gulf War Report. They then identified new studies published from 2003 to 2008 and considered whether these changed the conclusions in the IOM report. In the case of TCE and kidney cancer, this was the case. The Camp Lejeune committee considered six new cohort studies and two case-control studies (including Charbotel et al.). They concluded that several of these studies reported an increased risk of kidney cancer, but observed that the results were often based on a relatively small number of exposed persons and varied quality of exposure data and methodology. Given these data, the committee raised the classification for TCE to match the IOM conclusion of "limited" evidence for perchloroethylene.	N	N	N	N	N	N	N	N	N	Y	N
342	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	2.4.2.2	EPA, on the other hand, offered the summary conclusion of convincing human evidence, based on the "consistency" of increased kidney cancer across the different studies. The authors of these studies, however, do not agree with EPA's characterization of them. For example, the authors of Charbotel et al., the study EPA finds most compelling, state that the "study suggests an association between exposures to high levels of TCE and increased risk of [renal cell carcinoma]. Further epidemiological studies are necessary to analyze the effect of lower levels of exposure."	N	N	N	N	N	N	N	N	N	Y	N
343	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	2.4.2.2	Given the flaws in the IRIS Assessment, and the very different conclusion reached by the Academy in its Camp Lejeune report on the same body of data, the forthcoming evaluation under TSCA as amended should not rely on the IRIS Assessment's classification of TCE as "Carcinogenic to Humans."	N	N	N	N	N	N	N	N	N	Y	N
344	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	2.4.2.2	2. EPA Should Reassess Available Cancer Epidemiology Data, Given Publication of More Recent and Larger Studies on Worker Populations. The observation of an elevated but weak kidney cancer association reported by Charbotel et al. (2006) contrasts with other occupational studies which did not find an elevation in kidney cancer in industries using TCE as a metal degreaser, e.g., aircraft manufacturing, metal cleaning, etc., where exposures may be higher than for screw cutters. Lipworth and coworkers (2011) found no evidence of increased kidney cancer in a large worker cohort with multiple decades of TCE exposure and extended cancer follow-up evaluations. The aircraft manufacturing study involved a total cohort of 77,943 workers, of which 5,443 were identified as exposed to TCE. The study involved evaluations from 1960 through 2008, at which time 34,248 workers had died. Approximately 30% of the workers were hired before 1960 (60% born before 1940), 52% terminated employment by 1980, and approximately a third of the workers were employed for more than 20 years. The standardized incidence ratio (SIR) for kidney cancer in the TCE-exposed workers was reported as 0.66 (CI 95%: 0.38-1.07). This value for the SIR indicates that these workers were potentially less likely to get kidney cancer than the normal population (or at least had the same rate as the normal population – SIR of 1).	N	N	N	N	N	N	N	N	N	Y	N
345	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	2.4.2.2	More recently, two large Nordic country epidemiological studies, both of which had extensive follow-up of the cohorts, have likewise failed to find an association between TCE and kidney cancer. An SIR of 1.01 (0.70-1.42) was found by Hansen et al. (2013) for kidney cancer based on 32 cases out of a total of 997 cancer cases in a cohort of 5,553 workers in Finland, Sweden, and Denmark, indicating that rates were the same as the normal population. TCE exposures in this cohort were directly confirmed from urinary biomonitoring of the TCE metabolite trichloroacetic acid (TCA). However, overall TCE exposures were likely low in this cohort in that most urinary TCA measurements were less than 50 mg/L, corresponding to approximately 20 ppm TCE exposure. Thus, consistent with the conclusions of Bruning and Bolt (2000), this study indicates TCE is unlikely to be a low-dose kidney carcinogen.	N	N	N	N	N	N	N	N	N	Y	N
346	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	2.4.2.2	Similarly, no evidence of kidney cancer was found by Vlaanderen et al. (2013) in a recent follow-up examination of the Nordic Occupational Cancer cohort (Finland, Iceland, Norway, Sweden) in which statistically non-significant risk ratios (RR) of 1.01 (0.95-1.07), 1.02 (0.97-1.08), and 1.00 (0.95-1.07) were reported for a total of 4,145 renal cancer cases approximately equally distributed across three respective TCE exposure groups (tertiles) assigned from a job exposure matrix analysis. Finally, although a meta-analysis of 23 studies meeting criteria for study inclusion found a slightly increased simple summary association of TCE and kidney cancer, RR 1.42 (1.17-1.77), more detailed analyses of subgroups suggested no association, or possibly a moderate elevation in kidney cancer risk, and no evidence of increasing risk with increasing exposure. These more recent studies were not reviewed in the 2011 TCE IRIS assessment.	N	N	N	N	N	N	N	N	N	Y	N
347	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	2.4.2.2	3. EPA's reliance on Charbotel et al. (2006) Resulted in an Overly Conservative Estimate of Risk. The inhalation unit risk (IUR) value developed in the 2011 IRIS assessment was based primarily on epidemiology data from the case-control study on renal cell carcinoma (RCC) by Charbotel et al. (2006), discussed above. Although other epidemiological studies were used to derive an adjusted IUR estimate for the combined risk of developing RCC, NHL, or liver cancer, EPA concedes a lower level of confidence in both the NHL and liver cancer databases. While the Charbotel et al. study suggests a relationship between cumulative TCE exposure and RCC incidence, the reliability of the exposure estimates is a major concern.	N	N	N	N	N	N	N	N	N	Y	N
348	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	2.4.2.2	The National Academy of Sciences Committee that reviewed the draft IRIS assessment released in 2001 recommended that: "[t]here appear to be insufficient epidemiologic data to support quantitative dose-response modeling for trichloroethylene and cancer. The committee recommends that toxicologic data be used to fit the primary dose-response model(s) and that the available epidemiologic data be used only for validation. The committee does not believe that the available information is sufficient to determine the best dose-response model for trichloroethylene."	N	N	N	N	N	N	N	N	N	Y	N

349	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	2.4.2.2	EPA should follow the recommendation of the National Academy of Sciences, which referenced the Charbotel et al. (2005) final study report in its review of TCE. The authors' own conclusions that the study only "suggests that there is a weak association between exposures to TRI [TCE] and increased risk of RCC" argues against the existence of the robust relationship which should be required for a dose-response assessment that may be used as the basis for regulation.33 Footnote: 33 This concern was recognized by the European Chemicals Agency (ECHA) in its 2013 Chemical Safety Report on TCE: "[T]here are several concerns with this study that should be taken into consideration when assessing its use in risk assessment and hazard characterization. For example, potential selection bias, the quality of the exposure assessment, and the potential confounding due to other exposures in the work place. With respect to the potential for selection bias, no cancer registry was available for this region to identify all relevant renal cell cancer cases from the target population. Case ascertainment relied on records of local urologists and regional medical centers; therefore, selection bias may be a concern. Given the concerns of the medical community in this region regarding renal cell cancer (RCC) among screw cutting industry workers, it is likely that any cases of renal cell cancer among these workers would likely be diagnosed more accurately and earlier. It is also much more unlikely that an RCC case among these workers would be missed compared to the chance of missing an RCC case among other workers not exposed to TCE. This preference in identifying cases among screw-cutting industry workers would bias findings in an upward direction. Concerning the potential for other exposures that could have contributed to the association, screw-cutting industry workers used a variety of oils and other solvents. Charbotel et al. reported lower risks for TCE exposure and renal cell cancer once data were adjusted for cutting oils. In fact, they noted, 'Indeed many patients had been exposed to TCE in screw-cutting workshops, where cutting fluids are widely used, making it difficult to distinguish between cutting oil and TCE effects.' This uncertainty questions the reliability of using data from Charbotel et al. since one cannot be certain that the observed correlation between kidney cancer and exposure is due to trichloroethylene."	N	N	N	N	N	N	N	N	N	Y	N
350	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	2.4.2.2	The exposure assessment for the Charbotel study was based on questionnaires and expert judgment, not direct measures of exposure. Worker exposure data from deceased individuals were included in the study. In contrast to living workers, who were able to respond to the questionnaires themselves, exposure information from deceased workers (22.1% of cases and 2.2% of controls) was provided by surviving family members. The authors acknowledge that "this may have led to a misclassification for exposure to TCE due to the lower levels in the quality of information collected."	N	N	N	N	N	N	N	N	N	Y	N
351	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	2.4.2.2	Analysis of the data revealed evidence of confounding from cutting fluid exposure. Unfortunately, TCE and cutting oil were co-exposures that could not be disaggregated and the majority of the TCE exposed population, the screw cutters, could be expected to experience similar patterns of exposure for both TCE and cutting fluids (probably in aerosol form). Thus, the apparent dose-response relationship for TCE could be wholly, or in part, the result of exposure to cutting fluids.	N	N	N	N	N	N	N	N	N	Y	N
352	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	2.4.2.2	In their 2006 publication of the study results, the authors assigned cumulative exposures into tertiles (i.e., low, medium and high), yet the dose-response evaluation conducted as part of the IRIS assessment relied on mean cumulative exposure levels provided at a later date. Although the IRIS assessment references the email submission of the data to EPA, it provides no detail on the technical basis for the table, raising serious transparency issues.	N	N	N	N	N	N	N	N	N	Y	N
353	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	2.4.2.2	In an apparent acknowledgement of the uncertainty of the exposure information, Charbotel et al. (2006) included an evaluation of "the impact of including deceased patients (proxy interviews) and elderly patients (>80 years of age)" on the relationship between exposure to TCE and RCC. Interestingly, it was stated that "only job periods with a high level of confidence with respect to TCE exposure were considered" in the study, an apparent reference to the use of two different occupational questionnaires, one "devoted to the screw-cutting industry and a general one for other jobs." As the Adjusted Odds Ratio (OR) for the high cumulative dose group was actually higher in the censored subgroup than in the uncensored group [3.34 (1.27-8.74) vs 2.16 (1.02-4.60)], the authors suggested that "misclassification bias may have led to an underestimation of the risk."	N	N	N	N	N	N	N	N	N	Y	N
354	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	2.4.2.2	What the authors and EPA appear to have overlooked is that, in addressing the misclassification bias, Charbotel may also have altered the cumulative dose-response relationship. For example, in the censored subgroup there were now only 16 exposed cases (1 in the Low Group, 4 in the Medium Group and 11 in the High Group) with Adjusted ORs of 0.85, 1.03 and 3.34, respectively. If the dose-response relationship in this higher-confidence subgroup has changed, use of the lower-confidence group to calculate the IUR would require rigorous justification.	N	N	N	N	N	N	N	N	N	Y	N
355	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	2.4.2.2	4. EPA's Adjustment of the Kidney Cancer-Based IUR Value for TCE to Account for Potential Liver Cancer and Non-Hodgkin's Lymphoma (NHL) Endpoints is Not Scientifically Defensible and Needs to be Reconsidered. In addition to our concerns about the appropriateness of basing the IUR for TCE on epidemiology data, as described above, HSIA has serious concerns about the scientific appropriateness of adjusting the IUR derived from kidney cancer data to account for non-Hodgkin's lymphoma (NHL) and liver cancer. Derivation of the modified IUR is described in Section 5.2.2.2 of the IRIS Assessment. A recent review sponsored by HSIA concludes that it was not appropriate for EPA to adjust the IUR based on kidney cancer for multiple cancer sites because the available epidemiology data are not sufficiently robust to allow such calculations and the data that are available indicate that the IUR for kidney cancer is protective for all three cancer types. See Appendix 2 (attached) for a complete discussion of this issue.	N	N	N	N	N	N	N	N	N	Y	N
356	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	2.4.2.2	5. A Role for Glutathione Conjugate-derived Metabolites in TCE Kidney Toxicity and Cancer Risk Assessment Should be Reconsidered. The TCE IRIS Assessment relies in part on the conclusion that DCVG and DCVC, which are weakly active renal toxicants and genotoxicants, are formed in toxicologically significant concentrations following human exposures to TCE. This conclusion rests primarily on studies in which a relatively high blood DCVG concentration (100 nM) was observed in volunteers exposed for 4 hours to 50 or 100 ppm TCE. However, Lash et al. (1999) relied on a spectrophotometric chromatographic method analysis of TCE glutathione conjugate-derived metabolites which had substantial potential for detection of non-TCE-specific endogenous substances.	N	N	N	N	N	N	N	N	N	Y	N
357	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	2.4.2.2	In a published paper sponsored by HSIA (abstract attached as Appendix 3), the HPLC/UV method used by Lash et al. (1999) was found to overestimate the levels of DCVG in blood, liver, and kidney compared to the more specific and reliable HPLC/MS/MS method. The reason for this overestimation was an interfering peak that was primarily from endogenous glutamate. It is imperative that the analytical data used in human health risk assessments be as accurate and reliable as possible, particularly if those data are used as surrogates for exposure to estimate potential health effects in humans. Our findings suggest that DCVG formation may have been substantially overestimated based on the levels that were quantified by the HPLC/UV method. The implications of this apparent uncertainty are that the GSH pathway may play a more limited role, if any, in kidney toxicity from TCE exposure; and that the risk of kidney toxicity and carcinogenicity from TCE exposure, particularly in humans, may be overestimated and may be occurring by alterative mode(s) of action not inclusive of reactive GSH-derived metabolites.	N	N	N	N	N	N	N	N	N	Y	N

358	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	2.4.2.2	Since the publication of the IRIS Assessment in 2011, additional studies have evaluated the kidney concentrations of the oxidative and glutathione conjugate-derived metabolites of TCE in a variety of mouse strains administered five daily oral doses of 600 mg/kg TCE. Metabolites were quantitated two hours after the last daily dose; this time point was chosen because previous studies had shown that the approximate maximum plasma concentrations of TCA, DCA, DCVG and DCVC occurs two hours after an oral dose of TCE. Using a structure-specific HPLC-ESI-MS/MS method, Yoo et al. (2015) demonstrated that DCVG and DCVC were only a very small fraction of total metabolites quantitated in kidney. Trichloroethanol (TCOH) kidney concentrations were 2- to 4-fold greater than TCA, and TCA concentrations were 100- to 1,000-fold greater than DCA. Importantly, DCA concentrations were 100- to 1,000-fold greater than either DCVG or DCVC, resulting in the conclusion that TCE oxidative metabolism was up to five orders of magnitude greater than glutathione conjugate-derived metabolism.	N	N	N	N	N	N	N	N	N	Y	N
359	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	2.4.2.2	These findings were consistent with the earlier report from Kim et al. (2009), in which the time course of TCA, DCA, DCVG, and DCVC in serum was investigated following a single oral dose of 2,100 mg/kg TCE dose to male B6C3F1 mice. The total area under the curve (AUC) of TCA and DCA (oxidative metabolites) was 40,000-fold higher than the total AUC of DCVG and DCVC (glutathione conjugates). It should be noted that this study did not quantify the oxidative metabolite TCOH, which would have further increased the disparity of glutathione conjugate-derived metabolites relative to the oxidative-derived metabolites. These data demonstrate a dramatically lower function for glutathione-conjugate metabolism relative to oxidative metabolism in mice, despite the observation by Dekant (2010) (attached as Appendix 4) that mice generate DCVC at slightly higher rates than rats and greater than 10-fold higher than humans.	N	N	N	N	N	N	N	N	N	Y	N
360	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	2.4.2.2	The results of studies using structure-specific analytical methods for quantitation of DCVG and DCVC directly challenge the hypothesis that glutathione conjugate-derived metabolites plausibly account for the genotoxicity, renal cytotoxicity, and ultimate carcinogenicity in rodents. DCVC was only marginally cytotoxic (LDH release), if at all, when incubated at 0.2M (200,000 nM) with isolated renal cortical cells of male and female rats. This in vitro concentration is substantially higher than the approximate maximum kidney concentrations of 10 to 75 nM DCVC reported in various strains of mice given a high oral dose of 600 mg/kg TCE for 5 consecutive days (Yoo et al., 2015). A likely No-Observed-Adverse-Effect-Level (NOAEL) of 1 mg/kg-day was also reported for kidney toxicity in mice administered DCVC orally or intraperitoneally at a dose of 1, 10 or 30 mg/kg, once a week for 13 weeks, as indicated by a lack of change in serum blood urea nitrogen (BUN), weak tubule dilation, and no signs of necrosis. If, based on the data from Yoo et al. (2015), it is assumed that the ratio of formation of oxidative metabolites to glutathione conjugate-derived metabolites is 10,000:1, an implausibly high (occupational or general population) dose of 6,044 mg/kg TCE would be required to deliver a NOAEL dose of 1 mg/kg-day DCVC (1 mmol/kg-day TCE results in 0.0001 mmol/kg/day DCVC; 1 mg/kg-day DCVC = 0.0046 mmol/kg-day). These dose-toxicity calculations suggest that it appears toxicologically implausible that real-world exposures to TCE are capable of producing doses of DCVC sufficient to cause renal toxicity and carcinogenicity in mice.	N	N	N	N	N	N	N	N	N	Y	N
361	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Exposure	2.3.5, 2.6.1	IV. Miscellaneous. A. Worker and consumer exposure assessments should utilize all industry provided and publicly available information. The problem formulation document states that EPA will evaluate worker exposures to trichloroethylene in the TSCA risk evaluation from data that are publicly available, i.e, monitoring data from government agencies such as OSHA and NIOSH and from the published literature. It is recognized that these data may be from limited conditions of use or from out-or-date use/exposure scenarios. Thus, HSIA is submitting worker air monitoring data from trichloroethylene manufacturing facilities (attached as Attachment 5). We encourage EPA to utilize all available industry provided and publicly available information in its analysis of the exposure assessment in the risk evaluation.	N	N	N	N	N	N	N	N	N	Y	N
362	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Editorial	A.1	B. Trichloroethylene is subject to transportation regulations by the Department of Transportation (DOT) and the Pipeline and Hazardous Materials Safety Administration (PHMSA). Appendix A.1 of the problem formulation document lists the federal laws and regulations to which trichloroethylene is subject. There are also specific transportation regulatory requirements for trichloroethylene by the DOT and PHMSA; these regulations need to be added to the list of Federal Laws and Regulations in Appendix A.1. The DOT regulations provide instructions on trichloroethylene is to be transported by air, highway, rail or water. It defines the operational measures to ensure the health and safety of workers, as well as to ensure that no product is allowed to be released into the air, soil or water. PHMSA has the responsibility to maintain the hazardous material regulations. We hope that these comments will be useful to EPA as it develops the risk evaluation for trichloroethylene.	N	N	N	N	N	N	N	N	N	Y	N
363	EPA-HQ-OPPT-2016-0737-DRAFT-0104_Arkema	1	Exposure	2.2.2	Arkema is submitting the following information in regards to the Agency problem formulation efforts with respect to the Feedstocks that Arkema uses in the closed system manufacture of certain fluorinated gases in the US. Arkema believes that based on the totality of available evidence (industry provided and publicly available) it is appropriate for the Agency to exercise its discretion to exclude from its risk evaluation the use of the Feedstocks in the closed system manufacture of fluorinated gasses in the US because such activities pose only a de minimis exposure to humans or the environment. It appears that in making their determination, the Agency relied solely upon publicly available information and did not consider industry information that provides additional, important details about operations and use. Arkema, therefore, respectfully and strongly urges EPA to rely on all available data (industry provided and publicly available information) in making its exposure assessments – both in the problem formulations and in its risks evaluations.	N	N	N	N	N	N	N	N	N	Y	N
364	EPA-HQ-OPPT-2016-0737-DRAFT-0104_Arkema	1	Other	2.2.2	General Overview: The Feedstocks are used as intermediate raw materials in the synthesis of certain fluorinated gases. Specifically, DCM is used in the manufacture of Difluoromethane (CAS No. 75-10-5) (F-32). TCE is used in the manufacture of 1,1,1,2-Tetrafluoroethane (CAS No. 811-97-2) (R-134A). The Feedstocks are reacted with other raw materials in closed systems to create various fluorinated gasses. In this process, the Feedstock molecule is transformed during the formation of the new fluorinated gas. The fluorinated gasses are used as refrigerants (F-134A & F-32), foam blowing agents (F-134A and F-32) and solvents (F-32). Arkema uses the Feedstocks at its Calvert City, Kentucky facility solely for industrial purposes.	N	N	N	N	N	N	N	Y	N	Y	N
365	EPA-HQ-OPPT-2016-0737-DRAFT-0104_Arkema	1	Exposure	2.2.2	Arkema provided the Agency with an extensive description of our operations in connection with the use of the Feedstocks, including information regarding Arkema employee air monitoring, employee biomonitoring, ambient air monitoring, and emissions releases. To date, it appears that the data we provided was not considered during the exposure assessments. By not considering this additional information, the Agency is not taking into account all provided data sets, and the resulting actions will be incomplete and could significantly overestimate the potential exposures posed by Feedstock use in closed systems.	N	N	N	N	N	N	N	N	N	Y	N
366	EPA-HQ-OPPT-2016-0737-DRAFT-0104_Arkema	1	Exposure	2.2.2	Utilize All Avaiblable Data to Make Exposure Assessment: We urge the EPA to utilize the information that we and others in the industry provided and to use this information in addition to, and in conjunction with, publicly available information. The information provided by Arkema and the industry includes data on employee air monitoring, ambient air monitoring, biomonitoring, and emissions releases, and it does not appear that these important factors were considered when making the determination formulations. EPA appears to have aggregated exposure data across uses and such aggregation will yield greatly divergent exposure profiles – from completely emissive (solvent use) to closed systems (feedstock use). It is unclear whether EPA will do the same aggregation for the risk evaluations, and if the same methodology is used during the risk evaluations, it further increases the risk of overestimation of potential exposures posed by Arkema's use of the Feedstocks in closed systems.	N	N	N	N	N	N	N	N	N	Y	N

367	EPA-HQ-OPPT-2016-0737-DRAFT-0104_Arkema	1	Exposure	2.2.2	Conclusions. Based upon the totality of actual human and environmental exposure data (public and industry data) provided to the Agency, Arkema believes that the Agency has adequate and appropriate information to exercise its discretion not to include the use of TCE and DCM in the closed system manufacture of fluorinated gasses in the scope of its risk evaluations for these substances. As indicated above, industry evidence should be given equal weight as publicly available information. Industry often has resources at their disposal, that are unavailable to authors of much of the publicly available information and such information is necessary to complete an accurate picture of the risk of exposure to certain substances. If the Agency continues to include Arkema's use in its risk evaluation, Arkema strongly urges the Agency to utilize all available information, including information provided by industry, in conducting EPA's risk evaluations. Arkema appreciates the opportunity to provide written comments to the Office of Pollution Prevention and Toxics (OPPT) regarding rulemaking on problem formulations for the risk evaluations to be conducted under the Toxic Substances Control Act, and general guiding principles to apply systematic review in TSCA risk evaluations.	N	N	N	N	N	N	N	Y	N	Y	N
368	EPA-HQ-OPPT-2016-0737-DRAFT-0107_ACA	1	General	N/A	The American Coatings Association ("ACA") appreciates the opportunity to comment on proposed Problem Formulations for the first 10 chemical risk evaluations as required by the Frank R. Lautenberg Chemical Safety for the 21st Century Act ("Lautenberg Act"). We are committed to working with EPA to help ensure accurate risk evaluations under TSCA. The Association's membership represents 90% of the paint and coatings industry, including downstream users (or processors) of chemicals, as well as chemical manufacturers. Our membership includes companies that manufacture paints, coatings, sealants and adhesives whose manufacturing processes or products may be affected by the outcome of EPA's risk evaluations for several of the first ten chemicals. Similarly, our membership is concerned about EPA's process for chemical risk evaluations as established during review of this initial set of chemicals. ACA is eager to assist EPA in developing an effective system for chemical risk evaluations with successful implementation of the Lautenberg Act's mandates.	Y	N	N	N	N	N	N	N	N	N	N
369	EPA-HQ-OPPT-2016-0737-DRAFT-0107_ACA	1	General	N/A	ACA applauds EPA's willingness to interact with stakeholders during this process, ensuring that the Agency is taking steps in the right direction. ACA understands that implementation of the Lautenberg Act is not clear cut, and commends EPA on the solutions they have offered thus far. We are optimistic that through continued involvement with the public and stakeholder community, EPA will be successful in implementing a stronger, federal chemicals management program for years to come.	Y	N	N	N	N	N	N	N	N	N	N
370	EPA-HQ-OPPT-2016-0737-DRAFT-0107_ACA	1	Exposure	2.2.2	I. Establishing Federal Pre-emption for Conditions of Use ACA generally supports EPA's reasoned evaluation and exclusion of conditions of use from risk evaluation, based on the following (as stated in EPA's problem formulations): 1) Insufficient information to include an activity as a condition of use in a risk evaluation; 2) The condition of use is adequately controlled by other federal regulatory programs and therefore excluded from final risk evaluation; and 3) The condition of use does not require further analysis, but EPA will include it in the final risk evaluation based on existing information.	Y	N	N	N	N	N	N	N	N	N	N
371	EPA-HQ-OPPT-2016-0737-DRAFT-0107_ACA	1	Exposure, RegNex	2.2.2	Although in current risk evaluations, EPA has carefully described reasons for excluding conditions of use, ACA is concerned that a situation could arise in future risk evaluations where EPA excludes a condition of use in a manner that prevents EPA's risk evaluation from being comprehensive while limiting federal pre-emption. Under Section 18(a)(1)(B) of TSCA, states cannot establish a statute, criminal penalty or administrative action that restricts a use that EPA has made a final determination about (under Section 6(i)(1)), consistent with the scope of risk evaluation in Section 6(b)(4)(D). ACA is concerned that conditions of use relevant to the paint, coatings, sealants and adhesives industries, in future risk evaluations, will not be included in EPA's final risk evaluation. In effect, TSCA's pre-emption of state activities may not apply to such conditions of use, opening the door for a patchwork of state-level requirements. In certain instances, ACA would recommend that the Agency acknowledge uses that do not merit an unreasonable risk determination and include analysis supporting such a determination in a final risk evaluation. ACA recognizes that such an analysis would have to be made on a case-by-case basis. Similarly, ACA can also envision a situation where a condition of use is adequately controlled by an existing federal program, but EPA should nonetheless include it in the final risk evaluation to describe EPA's rationale for concluding the use poses no unreasonable risk. Such an approach might be appropriate where comprehensive mitigation of a risk factor by a federal program is uncertain or not universally accepted.	Y	N	N	N	N	N	N	N	N	N	N
372	EPA-HQ-OPPT-2016-0737-DRAFT-0107_ACA	1	Exposure	2.2.2	II. De Minimus Exposures and Final Risk Evaluations ACA can envision a situation where EPA could include de minimis exposures in a final risk evaluation, if only to document and integrate evidence of de minimis exposures to support a conclusion of no unreasonable risk. Such an analysis would promote comprehensive review while preserving pre-emptive effect of EPA's evaluation for the condition of use, rather than exclusion for de minimis exposures. Generally ACA supports EPA's exclusion for de minimis exposures in the current group of evaluations. For example, in its Problem Formulation for Carbon Tetrachloride, EPA excludes "industrial / commercial / consumer uses of carbon tetrachloride in commercially available aerosol and non-aerosol adhesives / sealants, paints / coatings and cleaning / degreasing solvent products" as a "conditions of use with de minimis exposure." EPA demonstrates that carbon tetrachloride is sufficiently restricted by other regulatory programs and is not a direct reactant or additive for the identified condition of use.	Y	N	N	N	N	N	Y	N	N	N	N
373	EPA-HQ-OPPT-2016-0737-DRAFT-0107_ACA	1	Exposure	2.2.2	III. Conclusion Noting these concerns for future evaluations, ACA supports EPA's identification of uses for inclusion and exclusion in the current set of problem formulations, while clearly distinguishing uses EPA will include in final risk evaluations without further analysis from those uses EPA will not include in final risk evaluations. ACA encourages EPA to continue its careful case-by-case analysis of conditions of use. ACA will submit comment in the future as appropriate.	Y	N	N	N	N	N	N	N	N	N	N
374	EPA-HQ-OPPT-2016-0737-DRAFT-0109_tire-manufacturers	1	General	N/A	I. Introduction The U.S. Tire Manufacturers Association (USTMA) is the national trade association representing major tire manufacturers that produce tires in the United States, including Bridgestone Americas, Inc., Continental Tire the Americas, LLC; Cooper Tire & Rubber Company; The Goodyear Tire & Rubber Company; Kuhmo Tire Co., Inc.; Michelin North America, Inc.; Pirelli Tire North America; Sumitomo Rubber Industries, Ltd.; Toyo Tire Holdings of Americas Inc. and Yokohama Tire Corporation. Effective May 23, 2017, the Rubber Manufacturers Association officially changed its name to the U.S. Tire Manufacturers Association (USTMA). USTMA members are committed to effective implementation of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA) and support a robust federal process for assessing chemicals in commerce. USMTA thanks EPA for the opportunity to provide comments on the problem formulation for TCE and the opportunity to share accurate use information with the agency about this substance. TCE is not used by USTMA member companies in the process of manufacturing tires, in tire manufacturing facilities, in tire retread facilities, or in USTMA member company retail and service center facilities.	N	N	N	N	N	N	N	N	N	Y	N

375	EPA-HQ-OPPT-2016-0737-DRAFT-0109_tire-manufacturers	1	Other	2.2.2	II. Overview of the problem formulation and market and use report for TCE. EPA's problem formulation document and market and use report for TCE outlines the conditions of use the agency plans to review during the risk evaluation for TCE. The market and use report includes two uses of TCE in tires: (1) as a processing solvent in the production of an antioxidant for tire manufacturing and (2) as a tire repair cement and solvent. [U.S. Environmental Protection Agency, Trichloroethylene Market and Use Report, March 2017]. USTMA surveyed our members and confirms that TCE is not found in antioxidants used by USTMA members to manufacture tires and is not used by USTMA member companies in the process of manufacturing tires, in tire manufacturing facilities, or in tire retread facilities. Additionally, USTMA surveyed members regarding the use of TCE in tire repair cements and solvents and can confirm that member companies that operate retail facilities and service centers do not use TCE in tire repair cements and solvents.	N	N	N	N	N	N	N	N	N	Y	N
376	EPA-HQ-OPPT-2016-0737-DRAFT-0109_tire-manufacturers	1	Other/Exposure	Apx C-1, Apx D-1	III. General comments on EPA's approach to problem formulations. A. Supporting tables. USTMA appreciates the supporting tables in the appendices for the various problem formulations for the first ten chemicals EPA will review. For TCE, these are "appendix C - SUPPORTING TABLES FOR INDUSTRIAL AND COMMERCIAL ACTIVITIES CONCEPTUAL MODEL" and "appendix D -SUPPORTING TABLE FOR CONSUMER ACTIVITIES AND USES CONCEPTUAL MODEL." These tables clearly communicate the uses of a chemical and the various routes of exposure EPA will assess in risk assessment. USTMA encourages the agency to continue use of these tables in problem formulation documents.	Y	N	N	N	N	N	N	N	N	Y	N
377	EPA-HQ-OPPT-2016-0737-DRAFT-0109_tire-manufacturers	1	Exposure, Policy	2.2.2, 2.5	B. Conditions of use. USTMA supports EPA's exclusion of uses outlined in the market and use report that are either past uses or uses that the agency does not have enough information to confirm the use of a substance. However, USTMA questions EPA's approach for each of the first ten chemicals to exclude certain exposure pathways that are under the jurisdiction of other regulatory programs; specifically, the Clean Water Act (CWA). USTMA encourages EPA to assess the scope of the CWA in regulating non-point sources. USTMA supports a robust federal approach to review aquatic routes of exposure versus a state-by-state approach for addressing non-point sources. Additionally, the problem formulation documents specify that EPA "may exclude conditions of use that the Agency has sufficient basis to conclude would present only de minimis exposures or otherwise insignificant risks (such as in a closed system that effectively precludes exposure or as an intermediate.)" U.S. Environmental Protection Agency, Document #EPA-740-R1-7014, Problem Formulation of the Risk Evaluation for Trichloroethylene (May 2018) at 19. USTMA encourages EPA to ensure the preemptive effect of TSCA by providing a safety determination for de minimis uses. For example, EPA could conclude that there is no unreasonable risk presented by the de minimis use of a chemical substance because the substance is in a closed loop system, a chemical intermediate or an impurity.	Y	N	N	N	N	N	N	N	N	Y	N
378	EPA-HQ-OPPT-2016-0737-DRAFT-0109_tire-manufacturers	1	Exposure	2.2.2	C. "Fit for purpose" The problem formulations for the first ten chemicals specify that each risk evaluation will be "fit-for-purpose," meaning that "not all conditions of use will warrant the same level of evaluation and the Agency may be able to reach some conclusions without comprehensive or quantitative risk evaluations." (Problem formulation for TCE at Page 13). USTMA supports a screening level approach to risk evaluation and conclusion that "not all conditions of use will warrant the same level of evaluation." We also support the agencies decision to "reach conclusions without comprehensive or quantitative risk evaluations." USTMA encourages EPA to issue safety determinations for uses as they are made by the agency. We support and encourage the agency to issue safety determinations about uses that do not pose a risk early in the risk evaluation process.	Y	N	N	N	N	N	N	N	N	Y	N
379	EPA-HQ-OPPT-2016-0737-DRAFT-0109_tire-manufacturers	1	General/Exposure	2.2.2	IV. Conclusion. USTMA thanks EPA for the opportunity to provide comments on the problem formulation process and accurate information on the use of TCE, one of the first ten chemicals under review through the Toxic Substances Control Act as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.	Y	N	N	N	N	N	N	N	N	Y	N
380	EPA-HQ-OPPT-2016-0737-DRAFT-0111_UAW	1	General	N/A	The International Union, UAW, representing one million active and retired members is grateful for the opportunity to comment on the above referenced document.	Y	N	N	N	N	N	N	N	N	Y	N
381	EPA-HQ-OPPT-2016-0737-DRAFT-0111_UAW	1	Exposure, Editorial	2.5.3.1-3, Appendix C	Inclusion and Further Analysis The UAW finds this document to be confusing. A literal reading of the document would suggest that the only pathway that EPA plans to include and further analyze in risk evaluation is aquatic species (i.e. aquatic plants) exposed via contaminated surface water. This is the only pathway mentioned in Section 2.5.3.1 whose title suggests it covers all such pathways. In addition, no occupational pathways are mentioned in 2.5.3.2 Pathways that EPA Plans to Include but Not Further Analyze. Nor are they mentioned in 2.5.3.3 Pathways that EPA Does Not Plan to Include in the Risk Evaluation. In fact, one can read the entire body of the document without getting any idea of whether EPA plans to analyze occupational exposures or not. The only indication in the entire document as to EPA's intentions is the column header in Appendix C entitled "Proposed for Further Risk Evaluation." The UAW takes it to be the case that wherever there is a "Yes" in this column, further risk evaluation will be done. The UAW requests that this document be revised with at least one additional sentence in Section 2.5.3.1 stating that all occupational pathways with a "Yes" in the appropriate column in Appendix C will be further analyzed.	N	N	N	N	N	N	N	N	N	Y	N
382	EPA-HQ-OPPT-2016-0737-DRAFT-0111_UAW	1	Exposure	2.3.5.1	Occupational Non-Users EPA states [p.39] "Occupational non-users are not directly handling TCE; therefore, skin contact with liquid TCE is not expected for occupational non-users, but skin contact with vapors is expected for occupational non-users." Based on this conclusion, Appendix C excludes a large number of Release/Exposure scenarios involving dermal contact of occupational non-users (ONU) with liquid TCE. It is unclear from the description of ONU whether workers performing maintenance activities on TCE contaminated equipment are considered by EPA to be workers or ONU.	N	N	N	N	N	N	N	N	N	Y	N
383	EPA-HQ-OPPT-2016-0737-DRAFT-0111_UAW	1	Exposure	2.3.5.1	The UAW strongly urges EPA to do one of the following: 1. Treat workers performing maintenance activities on TCE contaminated equipment as workers so that their dermal contact with TCE will be further analyzed OR 2. Reanalyze the following Release/Exposure scenarios to determine whether or not the ONU might include workers performing maintenance activities on TCE contaminatedequipment and include these scenarios in further analysis when and where they do: -TCE Manufacture - TCE as by-product - Manufacture of HFC's, HCL and muriatic acid - Manufacture of large, rigid plastic products - Industrial textile dyeing; and industrial textile finishing - Formulation of aerosol and nonaerosol products - Repackaging of import containers - Recycling of Process Solvents Containing TCE - Repackaging into large and small containers - Degreasing - Battery coat; and soap, cleaning compound, and toilet preparation manufacturing - Recovery of wax and paraffin from refuse; tin recovery from scrap metal; and phenol extraction from wastewater - Precipitant for beta-cyclodextrin manufacture - Disposal of TCE wastes	N	N	N	N	N	N	N	N	N	Y	N

384	EPA-HQ-OPPT-2016-0737-DRAFT-0111_UAW	1	Exposure, Editorial	2.3.5.1	In addition, EPA states that it does not intend to evaluate further dermal or inhalation exposure to TCE liquid or vapor for workers or ONU who work in the distribution of TCE-containing formulated products and/or of bulk TCE shipments because these exposures will be assessed during other lifecycle stages such as loading and unloading. It is not transparent where and how these exposures will be assessed. The UAW requests that EPA revise the document to make this information available in a transparent manner.	N	N	N	N	N	N	N	N	N	Y	N
385	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General	N/A	The City of New York (City) submits these supplemental comments regarding the above referenced Problem Formulations for Risk Evaluations for 10 chemicals (Problem Formulations) issued by the Environmental Protection Agency (EPA) on June 11, 2018 pursuant to Section 26(n)(2) of the Toxic Substances Control Act (TSCA), as amended in 2016 by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Chemical Safety Act). On July 13, 2018 the City submitted an initial set of comments and made a request for a four month extension of the deadline by which comments must be submitted. EPA provided an extension of the date by which comments must be submitted, from July 26, 2018 to August 16, 2018.3 The City now raises additional significant concerns and reiterates its request for an extension to review the Problem Formulations.	Y	N	N	N	N	N	N	N	N	N	N
386	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General	N/A	A. The City's Procedural Concerns. The ten Problem Formulations are complex technical documents that cumulatively are over 1,200 pages (not including the 2017 scoping documents). While EPA did grant an extension of the comment period from July 26, 2018 to August 16, 2018, the cumulative comment period of sixty-six days to review these materials is insufficient. Their complexity and length alone warrants a further extension of the comment period.	Y	N	N	N	N	N	N	N	N	N	N
387	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General	N/A	Further, EPA's choice to develop new Problem Formulations instead of amending their June 2017 scoping documents has resulted in inconsistencies between the documents that make them difficult to compare. Additionally, these scoping documents are not easily found on the regulations.gov sites for the individual Problem Formations for the 10 chemicals, and links are not available on the global website for the Problem Formulations. While EPA accounts for this choice by claiming they lacked sufficient time, it is unclear why that is the case. 7 Footnote: 7 As explained in the Scope Document, because there was insufficient time for EPA to provide an opportunity for comment on a draft of the scope, as EPA intends to do for future scope documents, EPA is publishing and taking public comment on a problem formulation document to refine the current scope, as an additional interim step prior to publication of the draft risk evaluation for trichloroethylene.".	Y	N	N	N	N	N	N	N	N	N	N
388	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General, Editorial	N/A	For example, Trichloroethylene (TCE) and Tetrachloroethylene (PERC) are among the most well-studied chemicals and are among those pollutants most prevalent in groundwater in the U.S. and elsewhere. It appears that the only difference between the scoping document and the Problem Formulation documents for these chemicals is that they have "refined" the conditions of use and exposure pathways, eliminating certain conditions of use and exposure pathways from consideration. It is unclear why these changes warranted a whole new document that impedes transparency, as it is difficult for the public to compare the Problem Formulations to the 2017 scope in order to understand the differences. It would be more helpful and easier for the public to understand any differences if EPA simply called the Problem Formulations amended scoping documents, rather than giving them new names and formats, insofar as scoping is an accepted mechanism to formulate problems for consideration in analysis.	Y	N	N	Y	N	N	N	N	N	Y	N
389	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General, Editorial	N/A	Additionally, EPA should make the scoping documents more easily accessible to the public, and provide explicit explanations of the differences between the scoping documents and Problem Formulations.	Y	N	N	N	N	N	N	N	N	N	N
390	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General	N/A	Additionally, TSCA requires EPA to "publish the scope of the risk evaluation to be conducted" but does not specifically require EPA to issue a problem formulation. Specifically, TSCA directs EPA to include in its scope the "hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider," while EPA purports to now do this in the Problem Formulations. However, because the statute directs the public to look at the scopes for this information, and not to problem formulations, interested stakeholders may not clearly understand revisions to the scope set forth in these Problem Formulations.	Y	N	N	N	N	N	N	N	N	N	N
391	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General	N/A	If, as stated by EPA "[t]he first 10 problem formulation documents are a refinement of what was presented in the first 10 scope documents" then EPA's assertion that "TSCA § 6(b)(4)(D) does not distinguish between scoping and problem formulation" is incorrect and contrary to law—TSCA Section 6(b)(4)(D) does not distinguish between scoping and problem formulation because it provides no explicit requirement for the publication of a problem formulation at all. This approach contradicts the Administrative Procedures Act by rebranding the scoping document into a Problem Formulation document, complicating and preventing the public from fully understanding the changes being made.	Y	N	N	N	N	N	N	N	N	N	N
392	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General, Editorial	N/A	The City again requests that EPA fix certain inadequacies in its docket, restart the comment period, and provide a four-month extension of the comment period to allow for additional public outreach and education. [Attachment A; comments dated 7/13/18] Additionally, because EPA does not clearly lay this out, the Agency suggests that it expects to continue to follow this process in the future, and the City of New York requests herein that any documents that EPA considers to have a scoping purpose be titled as a scope, show all revisions made to the new document that differ from any prior scope or problem formulation, and have those changes and all supporting documents easily available to the public.	Y	N	N	N	N	N	N	N	N	N	N
393	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.2.2, 2.3.5	B. The City's Substantive Concerns EPA is subject to TSCA's statutory directive to "regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards" and to "consider the environmental, economic, and social impact of any action the Administrator takes or proposes as provided under this chapter." EPA's failure to consider legacy exposure, as well as exposures that occur as a result of pathways that are not conditions of use, is arbitrary and capricious.	Y	N	N	N	N	N	N	N	N	N	N
394	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.2.2, 2.3.5	1. Legacy Contamination In addition to the City's concern about EPA's decision to remove from the risk evaluation certain activities and exposure pathways discussed below, the City is also concerned with excluding legacy uses from Problem Formulations and risk analyses. [p. 8-9, 20-21 of PF for asbestos] Many of the 10 chemicals have been used extensively in New York City, and are part of our built environment. The risks of exposure from legacy uses and disposal of these substances is noteworthy and ongoing.	Y	N	N	N	N	N	N	N	N	N	Y
395	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.2.2, 2.3.5	Asbestos is the prime example of a dangerous substance that is still widely present in older building materials and infrastructure. Legacy asbestos can become airborne and dangerous when it is disturbed—for example, by maintenance work and repairs, renovation, demolition, or accident. Legacy use of asbestos is a particular concern for workers who may disturb building materials or other infrastructure that contains asbestos. For example, asbestos-cement pipes and fittings have been widely used in America; water supply workers, plumbers, and others performing maintenance on such pipes can suffer exposure to airborne asbestos fibers when such pipes are drilled or otherwise cut. Legacy asbestos materials are a significant concern in the City, where multiple City agencies—namely, the Department of Sanitation, the Department of Environmental Protection, and the Department of Health and Mental Hygiene—regulate asbestos use, disposal, and abatement. Additionally, by excluding all consideration of the risks of Libby Amphibole asbestos—a type of asbestos derived from minerals mined near Libby, Montana that is no longer used in new products—EPA is simply ignoring the ongoing risks from Libby Amphibole that "remains in buildings as an insulating material."[p. 21 of PF for asbestos]	N	N	N	N	N	N	N	N	N	N	Y

396	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.2.2, 2.3.5	TSCA also does not adequately address legacy uses of PERC, methylene chloride, carbon tetrachloride, and TCE, as well as bystander exposure to PERC.17 These chemicals are possible or probable human carcinogens and toxic to various organs including the kidney and liver. They are very frequently found in groundwater and soil vapor throughout the City. This “legacy” directly impacts many New Yorkers due to widespread historic (and often current) use and the dense urban environment. These chemicals enter buildings through the soil vapor and frequently cause residents to breathe concentrations that are well above health-based guidance values. However, the extent of this problem is poorly studied and not adequately addressed byany federal acts. Because whole buildings or neighborhoods are sometimes affected, attempting to remediate these chemicals after they have entered into groundwater and soils is expensive and time consuming, and occurs only after building occupants, including children, are exposed to them. In order to prevent human health consequences, and an extraordinary waste of resources, TSCA must regulate them before they are legacy pollution.	N	N	N	Y	N	N	Y	Y	N	Y	N
397	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.2.2, 2.3.5	By disregarding the risks of legacy uses of all 10 chemicals, most importantly asbestos, PERC, methylene chloride, carbon tetrachloride, and TCE, EPA is excluding from its consideration the means by which many Americans may be exposed to these hazardoussubstances, and undercounting the net risks of exposure for all Americans.	Y	N	N	Y	N	N	Y	Y	N	Y	Y
398	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.2.2, 2.3.5	2. Unduly Narrow Scope In many other ways, EPA’s Problem Formulation has an unduly narrow scope of consideration. For example, EPA is also excluding from consideration all uses of asbestos not specifically identified by EPA, since EPA considers the use of asbestos in such “unspecified activities” as “not reasonably foreseen in the United States.” To the contrary, asbestos continues to make its way into a variety of unexpected products—for example, children’s crayons sold in the United States recently tested positive for asbestos. Similarly, although the Problem Formulation acknowledges that New Jersey identifies talc-containing asbestos as a hazardous substance, EPA does not discuss the risks of asbestos in talc at all.	Y	N	N	N	N	N	N	N	N	N	Y
399	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.6	To avoid overlooking unforeseen uses of asbestos EPA should acknowledge that it remains in use, and that therefore risks associated with legacy use and pathways that do not relate to its manufacture or the conditions of use defined by EPA may remain. These risks must be assessed in the risk analysis for EPA’s approach to be rational. In contrast, EPA simply excludes from its consideration all non-specified uses.	N	N	N	N	N	N	N	N	N	N	Y
400	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.3, 2.6.1.1	3. TCE Exposure Pathways First, EPA’s proposal to exclude from further analysis the risks of TCE exposure caused by land application of biosolids is based on incomplete and incorrect information. [p. 53 of PF] Instead of basing the exclusion on removal efficiencies and the physical chemical properties of TCE, in the City’s opinion, EPA should consider whether TCE is present in biosolids based on data. TCE has been historically present in biosolids in the parts per million range, but thanks to EPA regulation, pollution prevention measures, and other efforts and changes in use patterns, TCE is largely currently present in biosolids in only trace amounts, if at all. Therefore, while there may be no current pathway (so long as EPA regulation, pollution prevention measures, and other efforts and changes in use patterns remain effective in minimizing and working to eliminate TCE in wastewater and other processes that generate biosolids) should TCE contamination in biosolids become prevalent again, EPA should be required to consider exposure caused by land application of biosolids.	N	N	N	N	N	N	N	N	N	Y	N
401	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.3, 2.6.1.1	Generally, before determining that a pathway for a given media is not an exposure risk, EPA should cite data regarding the chemical’s presence or absence in the media of potential concern and revisit that determination to ensure that future exposures do not arise. Additionally, minimal risk levels can change over time. Following heightened concern about Per- and Polyfluoroalkyl compounds (PFAS) caused by the documented presence of PFAS in biosolids and in surface waters and soils following biosolid applications, EPA reduced its Health Advisory for PFASs to the 70 part per trillion range. Should EPA reduce advisory levels for any chemicals regulated under TSCA, EPA should be required to revisit exposure pathways that had earlier been discounted because of a chemical’s minimal presence.	Y	N	N	N	N	N	N	N	N	Y	N
402	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure, RegNex	Figures 2-2 through 2-4	Second, EPA’s rationale for excluding from consideration certain exposure pathways caused by direct releases and wastes from industrial, commercial, and consumer uses and the receptors that may encounter those exposure pathways and directly ingest contaminated water is flawed, or at least inadequately supported. The conceptual models presented in figures 2-2 through 2-4 of the TCE Problem Formulation assumes that wastewater or liquid wastes receive treatment from a wastewater treatment plant (WWTP) and that any direct impacts through an oral route are addressed by Safe Drinking Water Act (SDWA) regulations. Specifically, EPA states that “the drinking water exposure pathway for trichloroethylene is currently addressed in the SDWA regulatory analytical process for public water systems, EPA does not plan to include this pathway in the risk evaluation for trichloroethylene under TSCA.”[p. 54 of PF for TCE]	N	N	N	N	N	N	N	N	N	Y	N
403	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure, RegNex	Figures 2-2 through 2-4	The City disagrees with this exclusion for several reasons. First, at least with respect to consumer uses, not all consumer wastewater discharges to WWTPs. For example, in Suffolk County on Long Island, New York, which relies on water supply from a sole source aquifer and where there are private wells and over 350,000 septic systems, consumer or commercial use of TCE products may result in a direct discharge of TCE to groundwater that potentially impacts drinking water through private wells and community water supplies. The SDWA cannot not adequately address these exposures—the appropriate statute for minimizing TCE exposures in areas without WWTPS is TSCA. Second, the SDWA contains provisions for both an enforceable standard, the maximum contaminant level (MCL), as well as a goal for health protection—the maximum contaminant level goal (MCLG). MCLs are to be set as close to the MCLG as possible while also considering the economic feasibility of reaching the MCLG. In the case of TCE, the MCLG is zero, but the MCL (5 µg/L) was developed considering the practical quantitation limit at the time it was being promulgated, and is subject to a six year review and recommendation for reassessment.	N	N	N	N	N	N	N	N	N	Y	N
404	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure, RegNex	Figures 2-2 through 2-4	Therefore, while the SDWA may prevent exceedances of the MCL, TSCA regulation is necessary to continue to advance toward the MCLG of zero or future MCLs that are established based on our future ability to detect smaller levels of contamination. Third, EPA is including in the analysis in Figure 2-4 the impact of releases on aquatic species. However, the Clean Water Act directs EPA to establish ambient water quality criteria for the protection of human health through direct consumption of surface water and for direct consumption of human health and aquatic organisms. Therefore, the inclusion of this exposure pathway contradicts the justification EPA set forth for excluding other pathways-that other statutes are effective in addressing the potential exposure. The City is not suggesting that the impact of TCE via water on aquatic species should be not be further analyzed, instead the City believes that all pathways caused by "activities that EPA concluded do not constitute conditions of use" and legacy uses must be included.	N	N	N	N	N	N	N	N	N	Y	N
405	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General	N/A	C. Conclusion EPA is arbitrarily excluding several pathways from consideration in the Problem Fonnulations, including pathways that are addressed by other federal statutes, pathways caused by legacy uses, and pathways that do not relate to conditions of use, such as exposure to people who live or work in spaces that are co-located with or adjacent to facilities that use TSCA regulated chemicals. If people are exposed to the 10 chemicals as a result of several different pathways, then eliminating certain pathways from consideration will fail to accurately account for receptors' total exposure, thereby resulting in regulations that are insufficiently protective. This failure is exacerbated by the EPA's lack of transparency in describing the differences between these Problem Formulations and the initial 2017 scoping documents. Therefore, the City requests that EPA revise the Problem Formulations to include the aforementioned pathways, and any others that are similarly necessary to adequately evaluate exposure risk, republish the Problem Fonnulations as amended scoping documents, clearly identifying all revisions, and start the public comment period.	Y	N	N	N	N	N	N	N	N	N	N

406	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General	N/A	The City of New York (City) submits initial comments regarding the above-referenced Problem Formulations for Risk Evaluations for 10 chemicals (Problem Formulations) issued by the Environmental Protection Agency (EPA) on June 11, 2018 pursuant to Section 26(n)(2) of the Toxic Substances Control Act (TSCA), as amended in 2016 by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Chemical Safety Act). The City has significant concerns about the Problem Formulations, which ignore certain exposure pathways that are common in New York City, and therefore may result in regulations that will put New Yorkers at risk. These concerns are addressed more fully below. [Attachment A; comments dated 7/13/18]	Y	N	N	N	N	N	N	N	N	N	N
407	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General, Editorial	N/A	In addition, the City requests that EPA fix certain inadequacies in its docket, restart the comment period, and provide a four-month extension of the comment period to allow for additional public outreach and education, the development of a complete and navigable docket, and further consideration of the complex regulatory and scientific issues implicated in the Problem Formulations. [Attachment A; comments dated 7/13/18]	Y	N	N	N	N	N	N	N	N	N	N
408	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.2.2, 2.3.5	A. The City's Substantive Concerns The Problem Formulations relate to ten different chemicals used across a spectrum of applications and industries, many of which (including, Methylene chloride, Perchloroethene, and Trichloroethene) are used frequently in the City in facilities that, because of our dense urban environment, are co-located in or adjacent to buildings where other people, including sensitive receptors, use the buildings for residential or commercial purposes. Others are currently used with less frequency, but off-gas into the air of buildings because they are present in soil vapor or groundwater (for instance, Carbon tetrachloride and 1-Bromopropane). For instance, dry cleaners are often in residential buildings where children may live or be cared for, or next to schools. Often, these chemicals are used in mixed-use zoning districts where residential and commercial uses are permitted to exist adjacent to or co-located with manufacturing uses. Because of these uses, the City is concerned about the limitations that EPA has set forth in the Problem Formulations that exclude from consideration certain exposure pathways. [Attachment A; comments dated 7/13/18]	Y	Y	N	Y	N	N	Y	Y	N	Y	N
409	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.2.2, 2.3.5	First, the City has significant concerns about EPA's decision to remove from the risk evaluation certain activities and exposure pathways, including "activities that EPA concluded do not constitute conditions of use." [p. 21 of PF for PERC] This limitation deviates from the scope set forth in the June 2017 Scopes of Risk Evaluation, [Scope for PERC] which stated that EPA intended to "assess each use subcategory by identifying all potential sources of release and human exposure associated with that subcategory." [pp. 20-21 of Scope for PERC] By excluding activities and uses that are designated on a case by case basis as not constituting conditions of use,4 EPA will likely fail to consider potential exposures caused during manufacture and use of the product, such as accidental spills, or exposures that occur when the chemical is used properly when the facility is co-located with or adjacent to residential, educational, recreational, or commercial activities. For example, using trichloroethene (TCE) as a spot remover in a co-located dry cleaning facility on the ground floor may result in a resident on the floor above the facility being exposed to the TCE. [Attachment A; comments dated 7/13/18] Footnote: 4 "Conditions of use" are defined by the Administrator and he or she has the authority to exclude conditions on case-by-case basis.	Y	N	N	Y	N	N	N	N	N	Y	N
410	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.2.2, 2.3.5	Moreover, what is currently considered "proper use" of a chemical may change in the future. Painting walls with lead-based paint or using PCBs for myriad purposes in the 1950s was proper use, but we are still dealing with the ramifications of those uses today. TSCA was amended by the Chemical Safety act to ensure that the potential problems of chemicals would be recognized before they go into widespread commercial or industrial use or, for current chemicals, to reduce the current impacts. By excluding many avenues of exposure from evaluation, EPA may allow these problems to continue, or be exacerbated. [Attachment A; comments dated 7/13/18]	Y	N	N	N	N	N	N	N	N	N	N
411	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure, RegNex	2.2.2, 2.3.5	Second, the City objects to EPA's exclusion of "exposure pathways [covered] under regulatory programs of other environmental statutes, administered by EPA, which adequately assess and effectively manage exposures and for which long-standing regulatory and analytical processes already exist, i.e., the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA) and the Resource Conservation and Recovery Act (RCRA)." [p. 54 of PF for PERC] While other governing statutes often address the same chemicals as TSCA regulations, they are often (if not exclusively) most effective in regulating contaminants after they are already in soil, water and air, or are focused on controlling discharges at a pipe or stack. These statutes often cannot prevent contaminants from entering the water, air, or soil in the first place, and are not intended to, and do not, ensure that chemical products are used safely and effectively. By failing to consider exposure pathways that result from spills or potential consequences of proper use that cause a chemical to enter the water, air, or soil, EPA will fail to properly account for exposures to the public, including New Yorkers, that result from TSCA-regulated activities. [Attachment A; comments dated 7/13/18]	Y	N	N	Y	N	N	N	N	N	N	N
412	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.2.2, 2.3.5	New York City has significant soil vapor exposure resulting from extensive use of Carbon tetrachloride, Methylene chloride, Perchloroethene, and Trichloroethene6 within our borders. This contamination results in health consequences not only for workers in the source facility, but also for adjacent or co-located workers, residents, and children. By curtailing TSCA, there will be further opportunities for these chemicals to enter the soil, air, groundwater, and buildings, exposing nearby New Yorkers and requiring unnecessary remediation in the future. [Attachment A; comments dated 7/13/18] Footnote: 6 Note, while 1-Bromopropane is not often found in City soil vapor. However, if 1-Bromopropane becomes more widely used (e.g., as a replacement solvent for PCE in dry cleaning) then it would likely be more abundant in the soil vapor. The City is hopeful that TSCA risk evaluators will consider the full implications of 1-Bromopropane and its potential for being a future contaminant. Additionally, if chlorinated compounds are replaced with brominated solvents, then other common workplace exposures to brominated solvents will likely increase in the future because the workplace practices are unlikely to change. The City recognizes that in the 1-Bromopropane Problem Formulation, EPA discusses inhalation of the chemical by people occupying businesses co-located with dry cleaners, and states that EPA will consider various issues relating to the chemical's waste, disposal, and use that may impact other non-occupational bystanders. However the Problem Formulation does not specifically discuss the inhalation of 1-Bromopropane in co-located homes.	N	N	N	Y	N	N	Y	Y	N	Y	N
413	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.2.2, 2.3.5	Under both New York City's Community Right to Know Law, Local Law 26 of 1998, and Spill Bill, Local Law 42 of 1987, the City makes a concerted effort to educate facility operators on good housekeeping practices to prevent releases of chemicals from occurring. These local laws have helped protect City residents by monitoring facility owners and operators to ensure the safe and proper use of chemicals, and have served to protect the public and property from such chemical releases in the environment. However, the City's efforts must be complemented by EPA regulatory measures that set protective limits on the manufacture and use of these chemicals. These Problem Formulations have the effect of minimizing consideration paid by EPA to sensitive receptors' exposures. By intentionally turning a blind eye to the impacts on sensitive receptors, EPA risks frustrating enforcement of Local Laws 26 and 42, which the City has been enforcing for 30 years. If EPA were to weaken its regulation of these chemicals based on Project Formulations that don't sufficiently account for exposures to people who spend time adjacent to or co-located with regulated facilities, EPA is effectively undermining the City's ability to effectively protect the public and environment. [Attachment A; comments dated 7/13/18]	Y	N	N	N	N	N	N	N	N	N	N

414	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC		3	General	N/A	B. The City's Request for an Extension The City also notes, and objects, that the Federal Register directs the public to the docket at regulations.gov for access to materials relevant to the Notice and Problem Formulations but the docket is incomplete. For example, a recent search for the document titled "Application of Systematic Review in TSCA Risk Evaluations"7 did not identify the document on the docket. City staff contacted the relevant EPA contact listed in the Federal Register, who expressed surprise to learn that the document was not on the official docket web page. However, the document was still missing from the docket upon submission of these comments, and in any event, even if it were posted belatedly, it would not be available for the full comment period. [Attachment A; comments dated 7/13/18] Footnote: 7 While this document is not available on the official docket, it can be identified by an internet search.	Y	N	N	N	N	N	N	N	N	N	N
415	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC		3	General	N/A	Additionally, at the time of these comments, although some of the other docket numbers for the specifically referenced ten chemicals contained links to record documents, some did not, creating confusion. For example, Docket number EPA-HQ-OPPT-2016-732-0080, for PCE, shows the Problem Formulation document, but indicates that the comment period has closed. However, the Problem Formulation document is dated May 2018 and was posted in June 2018. [Attachment A; comments dated 7/13/18]	Y	N	N	Y	N	N	N	N	N	N	N
416	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC		3	General, Editorial	N/A	Considering that the docket is not complete, that there are five separate docket numbers assigned to various aspects of the Chemical Safety Act, and that EPA's website is confusing to the general public, it is unclear what EPA is soliciting comments on, where those and related documents are located, and when comments are due. EPA has not complied with required administrative procedures for public notice and comment. Illustrative of these issues, as of July 10, 2018 there were only two comments on record on regulations.gov, despite the significant numbers of people affected by the Project Formulations, which indicates that there has not been sufficient public outreach and education. Consequently, we request that EPA fix the inadequacies in its docket. We further request that EPA restart the comment period and provide a four month extension because the Project Fonnulations themselves are extraordinarily complex, and therefore, the consequences of their conditions and limitations demand diligent review that cannot be accommodated within the 45-daycomment period. [Attachment A; comments dated 7/13/18]	Y	N	N	N	N	N	N	N	N	N	N
417	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU		2	General	N/A	On behalf of North America's Building Trades Unions (NABTU), its fourteen affiliated national and international construction unions and the three million working people they represent, I am writing to provide comment on the Problem Formulation of the Risk Evaluation Documents for the priority chemicals. NABTU urges the EPA to examine the full range of risks that current exposures to the priority chemicals are posing to construction workers and the public. Construction workers are exposed to the priority chemicals and a comprehensive risk assessment is required to effectively understand how best to manage unreasonable health risks. NABTU's comments on EPA's New Chemicals Review Program under the Amended Toxic Substances Control Act (EPA-HQ-OPPT-2017-0585-0056) are attached.	Y	N	N	N	N	N	N	N	N	N	N
418	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU		2	General	N/A	These comments are submitted by North America's Building Trades Unions (NABTU) on behalf of its 14 affiliated national and international construction unions and the 3 million working men and women they represent. Many of these workers are regularly employed in building, maintaining, renovating, or demolishing structures, work that exposes them to a variety of products and chemicals. On behalf of these workers, NABTU is submitting comments on the Environmental Protection Agency's (EPA's) Problem Formulation of the Risk Evaluation Documents to urge EPA to examine the full range of risks that current exposures to priority chemicals are posing to construction workers and the public.	Y	N	N	N	N	N	N	N	N	N	N
419	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU		2	General	N/A	In 2016, through bipartisan effort, Congress passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act, reforming the Toxic Substances Control Act (TSCA). Congress amended TSCA because it understood that although the statute had been on the books since 1976, toxic substances continued to pose substantial risks to the public. Congress directed EPA to quickly assess whether "the manufacture, processing, distribution in commerce, use or disposal" of known toxic chemicals "presents an unreasonable risk of injury to health or the environment," including to "potentially exposed or susceptible subpopulations," in all of their "conditions of use." § 6 (a) and (b)(4)(A). In selecting toxins to assess, EPA is to start with "high-priority substances," defined as those that, "without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment." § 6(b)(1)(B). And if EPA finds that a particular toxic substance poses an unreasonable risk, it is to take action to limit or prohibit its use. § 6(a).	Y	N	N	N	N	N	N	N	N	N	N
420	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU		2	General	N/A	EPA has identified ten high-risk, high priority chemicals to be the first evaluated and regulated under the Frank R. Lautenberg Chemical Safety for the 21st Century Act: 1-bromopropane (1-BP), 1,4-dioxane, carbon tetrachloride, cyclic aliphatic bromide cluster (HBCD), methylene chloride, n-methylpyrrolidone (NMP), pigment violet 29, tetrachloroethylene (PERC), trichloroethylene (TCE), and asbestos. The group of these chemicals is referred to as the 'priority chemicals'. These comments focus on the priority chemicals; however, NABTU has submitted additional comments specific to asbestos.	Y	N	N	N	N	N	N	N	N	N	N
421	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU		2	Exposure, PESS	2.3.5	Construction workers are routinely exposed to many of the priority chemicals. The amendments to TSCA require EPA to assess the risks chemicals pose "to health or the environment," including to the health of "potentially exposed or susceptible subpopulation[s]." §6(b)(4)(A). NABTU fully supports EPA's decision to include worker exposures in the scope of the risk assessment as discussed in the Problem Formulation documents. However, as discussed in more detail below, we are concerned that several of the decisions EPA has made in its Problem Formulation for the 10 priority chemicals will undermine its ability to fully assess the risks these chemicals pose to construction workers.	Y	N	N	N	N	N	N	N	N	N	N
422	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU		2	Exposure, PESS	2.2, 2.3.5	As presented in previous NABTU comments concerning the scope of the risk assessment for the priority chemicals (e.g., EPA-HQ-OPPT-2016-0723-0006), construction workers are regularly exposed to a variety of chemicals, including the priority chemicals. Construction workers are exposed to the priority chemicals through an array of products, including adhesives, coatings, cleaning products, degreasers, lubricants and greases, cures and sealants, strippers, cutting and metalworking fluids, refrigerant flushes, insulations, surfactants, concrete admixtures, soldering flux, and welding anti-spatter. Construction workers often apply these chemicals in inclosed or poorly ventilated areas (e.g. stripping paint in an enclosed room) or under hot conditions (e.g. applying roof coatings in the summer) which can increase the risk for high level exposures.	Y	N	N	N	N	N	N	N	N	N	N
423	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU		2	Exposure, PESS	2.2, 2.3.5	Moreover, construction workers are often unaware that they are being exposed to these toxins. First, they may not know that products they are using contain these chemicals. And second, they may not even be aware that the products are in their work environment. Construction sites are complex operations with multiple trades coordinating and performing work in the same vicinity. Therefore, workers routinely encounter exposures generated by other trades, without necessarily being aware of or familiar with the attendant hazards. Additionally, construction workers routinely perform maintenance, renovation, and upgrade work in industrial facilities. These work setting pose additional challenges to the ones described already, in that chemical, energy, and manufacturing facilities use tens of thousands of chemicals and mixtures, all of which may not be communicated to the contracted workforce. These "bystander" exposures are an important route for EPA to consider when evaluating risk.	Y	N	N	N	N	N	N	N	N	N	N
424	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU		2	Exposure, PESS	2.2, 2.3.5	The wide variety of chemicals to which construction workers are exposed is evident from a pilot study completed by CPWR - The Center for Construction Research and Training in January 2018. The pilot study asked 196 safety and health trainers from four different construction unions to identify common chemical hazards encountered in their trades. The trainers identified 63 different common chemical hazards in their trade, including some of the priority chemicals. The results were instructive, as they revealed not only the large numbers and wide range of chemicals which construction workers regularly encounter, but they showed that even these well-informed trainers did not necessarily know which specific chemicals are present in the products they use. For example, while almost two thirds of trainers listed adhesives as a common hazard, less than one fifth reported 1-bromopropane, methylene chloride, perchloroethylene, or trichloroethylene as a common hazard, even though these chemicals are known components of some adhesives.	Y	Y	N	Y	N	N	N	Y	N	Y	N

425	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure	2.2, 2.3.5	Results from the survey related to the 10 priority chemicals are in Table 1, which is divided into two parts. The first part of the table lists chemicals specifically identified by the trainers. The second part lists products they identified, which may contain one or more priority chemicals including: • Adhesives may contain 1,4-dioxane, 1-BP, carbon tetrachloride, methylene chloride, NMP, PERC, or TCE; • Coil cleaner may contain 1,4-dioxane, 1-BP, carbon tetrachloride, methylene chloride, NMP, PERC, or TCE; • Degreaser may contain 1,4-dioxane, 1-BP, PERC, or TCE; • Flame retardant may contain HBCD; • Lubricants may contain 1,4-dioxane, methylene chloride, PERC, or TCE; • Paints and coatings may contain 1,4-dioxane, 1-BP, carbon tetrachloride, NMP, PERC, or pigment violet 29; and • Soldering flux may contain NMP. [Table 1: CPWR Pilot Survey Results of Construction Trainers – Common Chemical Hazards Frequency and Control Use, Priority Chemicals, p. 6 of EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU]	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	N
426	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure	2.2, 2.3.5	A comprehensive risk assessment is required to protect potentially exposed and susceptible subpopulations. The statute directs the Administrator to "conduct risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . under the conditions of use." §6(b)(4). Congress clearly intended the Administrator to assess the risks chemicals pose throughout their entire lifecycle, by defining the conditions of use to include all of the circumstances "under which a chemical substance is intended, known or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of." §3(4). Similarly, the statute specifies that the Administrator is to issue regulations addressing any "unreasonable risk" presented by the "manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or . . . any combination of such activities." §6(a).	Y	N	N	N	N	N	N	N	N	N	N
427	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure, Policy	2.2, 2.5	The Problem Formulation Documents show that EPA understands that a full risk assessment model includes considerations of all the uses, pathways, and routes that pose the greatest risk of injury to the health of potential "receptors." See, e.g., Figures 2-2, 2-3, and 2-4 of each Problem Formulation Document. The agency, however, has decided to exclude from its risk assessment certain aspects of the chemicals' life cycles that are particularly important sources of exposure for construction workers. For example, as NABTU has described in detail in its comments on the Problem Formulation Document for Asbestos, excluding from "conditions of use" any "legacy uses" of the priority chemicals will eliminate evaluation of significant sources of exposure for construction workers. See NABTU comments submitted under EPA-HQ-OPPT-2016-0736. In addition, EPA must evaluate exposures from known and reasonably foreseeable "conditions of use" in addition to intended uses. EPA has decided not to evaluate exposures from many commercial uses of various chemicals stating that the products are not advertised for consumers. See e.g., Problem Formulation Document for 1-BP at 19. However, despite how a product is advertised, it may be used by consumers, particularly small contractors. This is an important source of exposure as businesses with one to nine employees made up 81% of the construction industry in 2012.	Y	Y	N	N	N	N	N	N	N	N	Y
428	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure	2.3.5, 2.5.3	EPA has chosen to not evaluate exposures from ambient air, drinking water, ambient water, or disposal pathways. See e.g., Section 2.5.3.2 or 2.5.3.3 of the Problem Formulation Documents. In addition to occupational exposures, construction workers are individuals who live in communities, sometimes near worksites, breathing, cooking, drinking water, and enjoying time with friends and families outdoors. Ignoring these pathways ignores the home and community aspect of a worker's life.	Y	N	N	N	N	N	N	N	N	N	N
429	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure, Policy, RegNex	2.5	In addition to air and water, EPA has decided not to consider exposures arising from wastes, specifically stating that "EPA does not expect to include on-site releases to land from industrial non-hazardous and construction/demolition waste landfills". See e.g., Problem Formulation Document for 1-BP at 55, Problem Formulation Document for 1,4-dioxane at 45, Problem Formulation Document for TCE at 56, Problem Formulation Document for methylene chloride at 56, Problem Formulation Document for NMP at 51, Problem Formulation Document for PERC at 62. EPA justifies excluding this pathway from its risk assessment because wastes are primarily regulated under state programs, while also acknowledging that not all states require the same waste disposal protections. Yet, construction workers are routinely involved in handling, storage, and transporting waste materials that potentially contain the priority chemicals. All fourteen building trades unions participate in hazardous waste operations and emergency response (HAZWOPER) activities and Department of Energy site construction and remediation. Removal and disposal tasks can involve cutting, abrading, grinding, demolishing, digging, crushing, loading, and unloading resulting in exposure. It is only by first assessing whether these chemicals pose an unreasonable risk, and then by examining whether the state programs sufficiently address those risks that EPA can satisfy its statutory mandate to decide whether further regulation is required. See §6(a).	N	Y	Y	Y	N	N		Y	Y	Y	N
430	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure, PESS	2.2.2	EPA's decision not to assess products contaminated by the priority chemicals similarly eliminates a source of exposure for construction workers. Construction workers also are routinely called upon to use contaminated products, clean up contaminated environments, or remove structures built with contaminated products. Each of these tasks can generate chemicals and contaminated dusts, which is inhaled, absorbed through the skin and taken home on clothing. EPA cannot determine that these types of exposures would "present only de minimis exposure or otherwise insignificant risk" and should be excluded from evaluation without providing science-based evidence. See e.g., Problem Formulation Document for 1-BP at 21. Additionally, while contaminated products may not be an intended use, they are a "known or reasonably foreseeable use." §3(4). Worker exposures to contaminated products must be included in the scope for a comprehensive risk assessment of the priority chemicals to which construction workers, as a susceptible subpopulation, are reasonably expected to be exposed.	Y	Y	N	N	N	N	N	N	N	N	N
431	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure, Policy	2.2, 2.3.5	Narrowing the uses and pathways used to evaluate risk makes it less likely that risks needing to be controlled will be identified and addressed. Aggregate, long-term exposures resulting from multiple uses and pathways in addition to timing, frequency, context, location, duration, and magnitude are the basis of chronic disease risk assessment. These concepts have long been acknowledged and evaluated in both environmental and occupational health. EPA cannot make a predetermined conclusion that there is ' no risk' prior to a risk assessment as it has in the examples discussed in these comments. Ensuring that EPA has the knowledge to adequately control risk after a comprehensive risk assessment is the only way to effectively manage health risks.	Y	N	N	N	N	N	N	N	N	N	N
432	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	RegNex	2.2, 2.6	Other regulatory authorities do not justify forgoing the risk assessment mandated by TSCA. In its Procedures for Chemical Risk Evaluation Under the Amended TSCA (chemical evaluation procedures), EPA suggested that, "[d]uring the scoping phase, [it] may . . . exclude a condition of use that has been adequately assessed by another regulatory authority, particularly where the other agency has effectively managed the risks." 82 FR 33729. The chemical evaluation procedures further elaborate in Unit III.B.2 that an exposure may be excluded from evaluation if there is "a basis to foresee that the risk from the impurity would be 'de minimis' or otherwise insignificant." 82 FR 33730. However, the TSCA amendments require EPA to conduct a risk assessment before ceding responsibility to another regulatory agency or taking action itself under another of the statutes it administers. Moreover, there is no way EPA can determine whether another agency has "effectively managed the risks" or there is 'de minimis' exposure without first assessing the nature of the risks. NABTU therefore urges the agency not to exclude any pathways from its risk assessments because of the potential that the chemical may be regulated through other regulatory processes.	Y	N	N	N	N	N	N	N	N	N	N

433	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	RegNex, PESS	2.2, 2.6	The EPA administers a series of statutes intended to protect the health and safety of the public and the environment from toxic chemicals, including the Clean Water Act, Clean Air Act, Safe Drinking Water Act, Resource Conservation and Recovery Act, and Toxic Substances Control Act. Congress nonetheless amended TSCA in 2016, recognizing that despite these acts, and despite authority other regulatory agencies have over occupational and environmental pollutants, the public and environment were not adequately protected. Indeed, of particular resonance to NABTU and its affiliates, disproportionate health effects have been seen in worker populations, working families, and the public who live near worksites or other contaminated areas. Through the Lautenberg Act, Congress called on EPA to conduct comprehensive risk assessments to determine whether chemicals present unreasonable risk of injury to health of potentially exposed or susceptible subpopulations, and then, based on those assessments, to determine how best to address those risks.	Y	N	N	N	N	N	N	N	N	N	N
434	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	RegNex	2.2, 2.6	Congress gave the Administrator a number of options for addressing identified risks, including requesting that another regulatory agency take action (§9(a)) or taking action under other statutes EPA administers (§9(b)). However, that is a determination the Administrator is to make after first "determin[ing] that [there is] a risk to health or the environment associated with a chemical substance or mixture . . . ." It is only after conducting the necessary risk assessment that the Administrator may then consider whether the risk "may be prevented or reduced to a sufficient extent by action taken" either by other federal agencies or by EPA, under other federal laws it administers. If the Administrator believes another agency can adequately address the hazard, he is to submit a report to that agency, describing the risk and recommending a course of action – and if the other agency declines to act, the Administrator is required to do so. §9(a). If the Administrator determines instead that EPA has authority to address the identified risk under another of the statutes it administers, he is to decide under which statute he can best serve the public's interest. §9(b).	Y	N	N	N	N	N	N	N	N	N	N
435	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	RegNex	2.2, 2.6	Thus, the Act gives the Administrator discretion to determine how to effectively address risk, only after a risk assessment is done can the EPA scientifically determine whether other regulatory authorities have adequately prevented unreasonable risk to health of the populations protected under TSCA. In fact, EPA should evaluate the risk of the priority chemicals and then as a last step consult with other regulatory authorities in order to determine how to best manage health risks and effectively protect the public.	Y	N	N	N	N	N	N	N	N	N	N
436	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	RegNex, PESS	2.2, 2.6	In previous comments to EPA, NABTU discussed OSHA's limitations to protecting workers and the public to the level of protection TSCA demands from EPA. See Attachment A, EPA-HQ-OPPT-2017-0585-0056. TSCA provides EPA and OSHA co-authority over chemical exposures in the workplace. EPA should exercise its authority by consulting with OSHA to ensure that, in performing its risk assessments, occupational exposures are taken into consideration and understood, and that workers are adequately protected. In determining how to address unreasonable risks, EPA also needs to take into account that OSHA has limited resources and a high burden of proof for both creating and enforcing occupational standards.	Y	N	N	N	N	N	N	N	N	N	N
437	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	RegNex, PESS	2.2, 2.6	Conclusion Construction workers are exposed to a wide variety of chemicals in conditions that can contribute to high exposure levels. The amendments to TSCA require EPA to undertake a two-step process in addressing toxic chemicals: first assess the chemical to determine whether it poses an unreasonable risk; and then determine how best to address that risk. EPA must therefore must complete a comprehensive risk assessment that includes the full life cycle of chemicals and contamination exposures to effectively understand how best to manage unreasonable health risks. Moreover, EPA cannot predetermine that other authorities effectively manage risk before completing a comprehensive risk assessment. EPA should evaluate a chemical's risk to injury the health of potentially exposed and susceptible subpopulations and then determine under which authority can effectively prevent unreasonable health risks.	Y	N	N	N	N	N	N	N	N	N	N
438	EPA-HQ-OPPT-2016-0737-DRAFT-0113_CEH	1	General	N/A	On behalf of our 36,000 supporters, the Center for Environmental Health is pleased to submit the following comments about the "Problem Formulation of the Risk Evaluation for Trichloroethylene." We believe that the Environmental Protection Agency needs to make significant improvements if this process is to protect public health and be consistent with the Frank R. Lautenberg Chemical Safety for the 21st Century Act. We describe these improvements below.	N	N	N	N	N	N	N	N	N	Y	N
439	EPA-HQ-OPPT-2016-0737-DRAFT-0113_CEH	1	Human Health	2.4.2.1, 2.6	1. The problem formulation must include endocrine disruption as a noncancer hazard in Sec. 2.4.2.1. Hormone disrupting chemicals (endocrine disruptors) are a significant public health concern because some cause adverse effects at environmentally relevant exposures. For an example of trichloroethylene acting as an endocrine disruptor, see Kanada, M; Miyagawa, M; Sato, M; Hasegawa, H; Honma, T. (1994). Neurochemical profile of effects of 28 neurotoxic chemicals on the central nervous system in rats (1) Effects of oral administration on brain contents of biogenic amines and metabolites. Ind Health 32: 145-164. EPA's Chemistry Dashboard notes that "no endocrine disruption relevant data" is currently available for trichloroethylene. This data gap must be filled.	N	N	N	N	N	N	N	N	N	Y	N
440	EPA-HQ-OPPT-2016-0737-DRAFT-0113_CEH	1	Exposure, PESS	2.3	2. The problem formulation must require aggregate exposure assessments that include exposures caused by conditions or products not regulated by TSCA. While exposures from current use of products is important, exposure assessments must include aggregate exposure via contaminated water, soil and air, and products that are no longer manufactured but are still in use, regardless of the source of this contamination. Aggregate exposure assessment is widely used in risk assessment. Failure to use an aggregate exposure assessment could significantly underestimate exposure, including the exposure to vulnerable subpopulations. The use of aggregate exposure assessment was recommended to the Environmental Protection Agency by the agency's Children's Health Protection Advisory Committee.	Y	N	N	N	N	N	N	N	N	Y	N
441	EPA-HQ-OPPT-2016-0737-DRAFT-0113_CEH	1	Human Health, PESS	2.3.5, 2.5, 2.6	3. The problem formulation must require use of lifestage analysis when assessing risks to children. Each stage of childhood and adolescence differs from each other and from adults in significant ways. Lifestage analysis incorporates differences in anatomy, physiology, toxicokinetics, diet, environment, and behaviors that are relevant in a risk assessment. The Environmental Protection Agency developed a framework for lifestage analysis in 2006 and the use of lifestage analysis was recommended to the Environmental Protection Agency by the agency's Children's Health Protection Advisory Committee.	Y	N	N	N	N	N	N	N	N	Y	N
442	EPA-HQ-OPPT-2016-0737-DRAFT-0113_CEH	1	Human Health, PESS	2.4, 2.6	4. The problem formulation must require complete testing for neurotoxicology and developmental toxicology. EPA's Chemical Dashboard notes that there currently is "no developmental toxicity data available" for trichloroethylene. Similarly, there is "no neurotoxicology data available." Both types of data are important, and critical for assessing risks to children, a vulnerable subpopulation. The need for these types of data was highlighted by the Children's Health Protection Advisory Committee.	N	N	N	N	N	N	N	N	N	Y	N
443	EPA-HQ-OPPT-2016-0737-DRAFT-0113_CEH	1	General	N/A	6. The problem formulation must require use of Integrated Risk Information System assessments when available. Trichloroethylene was comprehensively assessed by IRIS in 2011. This assessment should be the basis of the current process.	N	N	N	N	N	N	N	N	N	Y	N
444	EPA-HQ-OPPT-2016-0737-DRAFT-0113_CEH	1	General, Policy	N/A	7. Problem formulations are not an authorized step in the TSCA risk evaluation process and cannot be used to revisit issues of scope after the Agency has issued a scoping document. The problem formulations on the 10 chemicals are unlawful under TSCA because they go far beyond the scoping documents in excluding uses, exposures and hazards from the risk evaluations.	Y	N	N	N	N	N	N	N	N	N	N

445	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General	N/A	Comments of Safer Chemicals Healthy Families et al. on Risk Evaluation Problem Formulation Documents for Ten Chemical Substances under the Toxic Substances Control Act Safer Chemicals Healthy Families (SCHF) and the undersigned groups submit these comments on the problem formulations developed by the Environmental Protection Agency (EPA) on the initial 10 chemicals selected for risk evaluations under the newly enacted Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA). SCHF leads a coalition of national and grassroots organizations committed to assuring the safety of chemicals used in our homes, workplaces and the many products to which our families and children are exposed each day. SCHF and its partners took a leadership role during the LCSA legislative process, advocating the most protective and effective legislation possible to reduce the risks of toxic chemicals in use today. These comments address crosscutting legal and policy issues common to the 10 chemicals as well as several chemical-specific issues. We are submitting our comments to all ten of the EPA dockets. The comments build on earlier SCHF submissions, including our September 19, 2017 comments on the EPA scoping documents on the 10 chemicals. Many SCHF partner organizations are also commenting on the problem formulations and we support these comments.	Y	N	N	N	N	N	N	N	N	N	N
446	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General	N/A	Organizations joining these comments are: Alaska Community Action on Toxics, Alliance of Nurses for Healthy Environments, Asbestos Disease Awareness Organization, Center for Environmental Health, Clean and Healthy New York, Clean Production Action, Clean Water Action (National), Clean Water Action (Connecticut), Colorado PIRG (CoPIRG), Earthjustice, Environmental Health Strategy Center, Healthy Building Network, League of Conservation Voters, Learning Disabilities Association of America, Maryland PIRG, Natural Resources Defense Council, Science and Environmental Health Network, Texas PIRG (TexPIRG), Toxic-Free Future, U.S. PIRG, United Steelworkers, WashPIRG, WE ACT for Environmental Justice, Women for a Healthy Environment	Y	N	N	N	N	N	N	N	N	N	N
447	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General	N/A	OVERVIEW Through LCSA, Congress amended the Toxic Substances Control Act (TSCA) to establish a new framework for conducting timely, comprehensive and science-based risk evaluations for chemicals of concern. The law provides that EPA's evaluations must be strictly risk-based and must result in a definitive determination of whether the evaluated substance as a whole presents an unreasonable risk of injury to health and the environment across its life cycle, without regard to cost and other non-risk factors. In conducting risk evaluations, EPA must address risks not only to the general population but also to "potentially exposed or susceptible subpopulations," including the elderly, children, pregnant women and workers. On December 19, 2016, as required by section 6(b)(2)(A) of TSCA, EPA selected 10 chemicals for initial risk evaluations. These precedent-setting evaluations address substances with widespread exposure and known health hazards. How EPA evaluates the risks of these chemicals will be critical to whether the public and policymakers are fully informed about the threats they pose to health and the environment. This in turn will determine whether EPA follows through with effective risk reduction measures under section 6(a) of TSCA that protect at-risk populations. The initial evaluations will also lay the groundwork for overall TSCA implementation and thus determine whether EPA establishes the robust and protective chemical risk management program that LCSA calls for.	Y	N	N	N	N	N	N	N	N	N	N
448	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure	N/A	Unfortunately, the 2017 scoping documents and more recent problem formulations make it increasingly apparent that the initial 10 evaluations will fall far short of the expectations of Congress and the requirements of the law. Through a combination of questionable exclusions and loopholes, failure to require necessary testing, deviations from accepted scientific methods and refusal to accept previous peer reviewed determinations of risk, the Agency is on a path to produce evaluations that ignore important exposure pathways and at-risk populations, disregard evidence of adverse effects and reach misleading and incomplete conclusions that understate risks and weaken public health protection.	Y	N	N	N	N	N	N	N	N	N	N
449	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Systematic Review	N/A	The many shortcomings of the scoping documents and problem formulations are compounded by the June 11 TSCA document for applying "systematic review" methods in the TSCA risk evaluations. As explained in our separate comments on this document, it would require data on the 10 chemicals to be reviewed using an arbitrary set of numerical criteria for study quality that has not been peer reviewed and is in conflict with other systematic review approaches used within EPA and by other federal agencies that have been endorsed by authoritative bodies like the National Academy of Sciences (NAS). Application of the TSCA systematic review document will unjustifiably restrict the body of evidence that informs EPA judgments about risk and hamper the Agency's ability to use the most relevant and meaningful data for decision-making on the 10 chemicals.	Y	N	N	N	N	N	N	N	N	N	N
450	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General	N/A	Because the 10 risk evaluations are likely to deviate dramatically from the goals of the law and take a large step backward in protecting public health, EPA should put them on hold, rethink how they are being conducted, and reinitiate them in accordance with the law and principles of sound science.	Y	N	N	N	N	N	N	N	N	N	N
451	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	SUMMARY OF KEY POINTS As described more fully in the body of these comments, we have the following fundamental concerns about the approach to risk evaluation reflected in EPA's scoping documents and problem formulations: • Congress intended the scope of risk evaluations to be defined within six months after their initiation. Problem formulations are not an authorized step in the risk evaluation process and cannot be used to revisit issues of scope after the Agency has issued a scoping document in accordance with section 6(b)(4)(D). The problem formulations on the 10 chemicals are unlawful under TSCA because they go far beyond the scoping documents in excluding uses, exposures and hazards from the risk evaluations. (Section I, page 6)	Y	N	N	N	N	N	N	N	N	N	N
452	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	RegNex	2.3	• In direct contrast to the scoping documents, all the problem formulations provide that EPA will not consider environmental exposure pathways that could be addressed under other laws administered by EPA. This approach would remove all environmental exposure pathways – a significant contributor to human health risk for many chemicals – from the TSCA risk evaluation process. This dramatic narrowing of TSCA's scope is contrary to the plain language of the law and will defeat the central purpose of TSCA reform – to conduct comprehensive risk evaluations on ubiquitous chemicals that examine the impacts on health and the environment of all of the diverse pathways and modes of release that may result in harm. (Section II, pages 7-12)	Y	N	N	N	N	N	N	N	N	N	N
453	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure	2.3	• In an extension of this approach, several of the problem formulations indicate that EPA will not evaluate the risks of general population exposure to the 10 chemicals. However, if the presence of a chemical in environmental media – and therefore exposure to the chemical by the general population – is attributable to its "conditions of use," there is no basis for excluding this background level of exposure from EPA's risk evaluation. Moreover, EPA cannot perform its obligation under the law to "integrate and assess" information on exposure if it ignores the contribution of general population exposure to the overall risk that a chemical poses to subpopulations that have additional sources of exposure. (Section III, pages 12-13)	Y	N	N	N	N	N	N	N	N	N	N
454	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure	2.3	• More broadly, neither the scoping documents nor the problem formulations shed any light on how EPA risk evaluations will account for multiple pathways of exposure by the general population or subpopulations. Instead, it appears that EPA will examine each source of exposure in isolation and will not consider either the combined effect of multiple exposures or the contribution of environmental releases to overall exposure and risk. This is a violation of TSCA. (Section IV, pages 13-14)	Y	N	N	N	N	N	N	N	N	N	N
455	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Exposure	2.2, 2.3	• Despite the deep concerns of commenters, the problem formulations reaffirm EPA's exclusion from its risk evaluations of ongoing use and disposal of chemical products that are no longer being manufactured (so-called "legacy uses"). This use and disposal clearly falls within the TSCA definition of "conditions of use" and its exclusion violates the plain language of the law. As the case of asbestos illustrates, discontinued products may be ubiquitous in the built environment and their contribution to current and future exposure and risk may greatly dwarf that of the few products that remain in commerce. To ignore this source of risk would deprive the public, scientists and regulators of important information about threats to public health and prevent policymakers from taking meaningful action to protect at-risk populations. (Section V, pages 14-16)	Y	N	N	N	N	N	N	N	N	N	Y

456	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Exposure	2.2, 2.3	• Further narrowing the scope of risk evaluations, EPA has determined that it will not address recently discontinued uses of chemicals. The goals of TSCA would be defeated if manufacturers of unsafe chemicals could circumvent scrutiny simply by ceasing production for specific uses before EPA completes a risk evaluation of those uses and then later re-entering the marketplace free from any restriction or determination of risk. This scenario is of particular concern where the product phase-out is in response to agency scrutiny and intended to avoid the consequences of an adverse risk finding and subsequent regulatory action. Although EPA claims that discontinued uses are not "conditions of use" as defined in TSCA, the future resumption of these uses can be "reasonably foreseen" and thus would satisfy the statutory definition. By including such uses in its risk evaluation, EPA could then ban or restrict them permanently under section 6(a), providing certainty to the marketplace and long-term public health protection. (Section VI, pages 16-18)	Y	N	N	N	N	N	N	N	N	N	N
457	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Human Health, Eco Health	2.4	• Our groups have repeatedly called for EPA to identify data gaps that limit its ability to reach definitive conclusions about the health and environmental effects of the 10 chemicals. However, the problem formulations make a minimal effort to identify the absence of data on the 10 chemicals and address how lack of information will impact the conclusions reached in the risk evaluations. In the face of material data gaps, an unqualified conclusion that a chemical does not "present an unreasonable risk of injury" to health could not be defended under TSCA and would misinform the public about the chemical's safety. Thus, EPA should be explicit about the health and environmental end-points that lack adequate data and exclude these end-points from its determinations of unreasonable risk. It should also use its TSCA authorities to require manufacturers to conduct testing to develop adequate data for a defensible risk evaluation so that future assessments can be informed by a comprehensive dataset. (Section VII, pages 18-23)	Y	N	N	N	N	N	N	N	N	N	N
458	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Exposure	2.2, 2.3	• The problem formulations indicate that conditions of use that present de minimis risks will not be further analyzed or addressed in risk evaluations. However, EPA has provided no general criteria for determining levels of exposure that are insignificant. Nor has it provided any information to demonstrate that the uses it plans to drop lack meaningful exposure potential, either in themselves or in relation to their contribution to overall exposure. EPA may have some latitude to devote greater effort to some exposure scenarios than others, but this does not excuse ignoring particular conditions of use based on the unsubstantiated claim that their risks are negligible. (Section VIII, pages 23-24)	Y	N	N	N	N	N	N	N	N	N	N
459	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Exposure, Human Health	2.3, 2.4	• As the asbestos risk evaluation illustrates, EPA has also dropped from consideration significant health end-points known to be linked to exposure to the chemical. This omission is likewise contrary to TSCA's comprehensive approach to evaluating risk. (Section IX, pages 24-25)	Y	N	N	N	N	N	N	N	N	N	Y
460	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General	N/A	• Six of the 10 chemicals – asbestos (and Libby amphibole asbestos), trichloroethylene (TCE), methylene chloride (MC), carbon tetrachloride (CTA), perchloroethylene (PERC) and 1,4-dioxane – have been assessed under the EPA Integrated Risk Information System (IRIS). The IRIS process is the Agency's authoritative mechanism for reviewing available studies and characterizing the health effects of chemicals. The problem formulations, however, indicate that EPA will revisit the interpretation of studies already evaluated in IRIS using its highly questionable TSCA "systematic review" method that has not been peer reviewed. This may lead to departures from IRIS determinations of the "best available science" and "weight of the evidence." Reopening IRIS findings would harm the public by prolonging uncertainty on issues that have been addressed and resolved through an authoritative and transparent process. In rare cases where significant new data (since the IRIS assessment) are available, the EPA TSCA program should rely on the IRIS program to review, assess, and if appropriate incorporate any new information using a systematic review method that is consistent with the state of the science. (Section X, pages 25-28)	N	N	Y	Y	N	N	Y	Y	N	Y	Y
461	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Policy, Exposure	2.2	• EPA has proposed to ban certain uses of TCE and N-methylpyrrolidone (NMP) under TSCA section 6(a) based on comprehensive exposure and risk assessments of these uses, including its peer reviewed IRIS assessments on TCE. However, the problem formulations indicate that EPA intends to reopen these completed assessments and delay regulatory action despite serious threats to public health. This is unjustified and unnecessary. EPA should finalize the proposed rules without delay. (Section XI, pages 28-29)	N	N	N	N	N	N	N	N	Y	Y	N
462	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	RegNex	2.3	• Occupational exposure is significant for nearly all of the 10 chemicals and should be a major focus of EPA's risk evaluations. The problem formulations indicate that when evaluating occupational risks, the Agency will heavily weigh applicable workplace standards. Although these standards may be relevant, EPA should not presume that they are fully protective of workers or that their existence can be equated with the absence of unreasonable risk. OSHA and EPA apply differing standards of protection by law; several OSHA standards are obsolete and do not reflect best available science; OSHA standards do not cover all workers with exposure to regulated chemicals; compliance with OSHA standards is uneven and variable; and as EPA has recognized, some of the industrial hygiene strategies embodied in OSHA standards – such as labels and respirators – are known to be of limited effectiveness in protecting workers. EPA should explicitly recognize these considerations in determining whether risks to workers are unreasonable under TSCA. (Section XII, pages 29-32)	Y	N	N	N	N	N	N	N	N	N	N
463	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	I. The Problem Formulations Have No Basis in the Law and Improperly Narrow the Scope of the 10 Risk Evaluations Section 6(b)(4)(D) of amended TSCA provides that, "not later than 6 months after the initiation of a risk evaluation," EPA must "publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and the potentially exposed or susceptible subpopulations the Administrator expects to consider." There is no authorization in the law for issuing a "problem formulation" document at a later point in time to further refine, expand or narrow the scope of the risk evaluation. Nor is this step identiifed in EPA's final risk evaluation framework rule issued under TSCA section 6(b)(4)(B).	Y	N	N	N	N	N	N	N	N	N	N
464	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	Nonetheless, when it released its scoping documents for the 10 chemicals in June 2017, EPA announced that it was also developing problem formulations. It justified this step on the basis that it had been unable to process all the information gathered during the scoping process and the scoping documents were not as "refined or specific" as EPA had hoped. Although the problem formulations may have performed a useful role under these unique circumstances, we do not support repeating this step for additional risk evaluations that EPA conducts. The intent of Congress was to provide clear notice to the public of the scope of risk evaluations within six months after they are initiated. This goal will be undermined if EPA retains the discretion to revisit issues of scope throughout the risk evaluation process and to continuously modify the hazards, uses and exposures that its evaluations will address.4 Thus, problem formulation should be a one-time activity, limited to the special case of the first 10 chemicals, and not part of the risk evaluation process in the future. Footnote: 4 Thus, instead of taking comments on proposed scoping documents and addressing them in final scoping documents issued six months after a risk evaluation is initiated, EPA is now requesting comments on scope issues 20 months into the risk evaluation process. EPA plans to release draft risk evaluations by the end of 2018. Thus, it will be unable to review the comments and modify the evaluations without delaying their completion. In practice, this creates a high likelihood that the comments will be ignored. EPA admits as much by acknowledging that it plans to respond to the comments only when the risk evaluations are final.	Y	N	N	N	N	N	N	N	N	N	N

465	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	2.5	We are also concerned that the problem formulations on the 10 chemicals go far beyond the scoping documents in excluding uses, exposures and hazards from the risk evaluations. Not only are these exclusions not justified under TSCA5 but they narrow the evaluation significantly after its scope had been established in accordance with section 6(b)(4)(D). Since problem formulation is not a recognized step in the risk evaluation process or a substitute for scoping under LCSA, it cannot be used to narrow a risk evaluation's scope after-the-fact. Thus, the additional exclusions established in the problem formulations are unlawful. Footnote: 5 EPA's final risk evaluation rule, in contrast to its proposal, would permit the Agency to select which conditions of use to address in risk evaluations. 82 Fed. Reg. 33726 (July 20, 2017). SCHF and several of its partner organizations argued in their comments on the proposal that the law requires the Agency to address all conditions of use in its evaluations. Along with several other groups, SCHF is challenging EPA's contrary interpretation in its petition for judicial review of the risk evaluation rule. Safer Chemicals Healthy Families v. EPA, 17-72260 (9th Cir.) Regardless of the outcome of this challenge, we believe that EPA has no basis to narrow the risk evaluation to exclude conditions of use once they have been included in its scope.	Y	N	N	N	N	N	N	N	N	N	N
466	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	RegNex, Exposure	2.3, 2.4	II. EPA's Extreme Approach of Removing All Environmental Exposure Pathways from Risk Evaluations Is Contrary to the Plain Language and Structure of TSCA and Will Defeat the Central Purpose of TSCA Reform In direct contrast to the scoping documents, all 10 of the problem formulations provide that EPA will not evaluate the risks of "exposure pathways that are under the jurisdiction of regulatory programs and associated analytical processes carried out under other EPA-administered environmental statutes – namely, the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA), and the Resource Conservation and Recovery Act (RCRA)."6 EPA's rationale for this blanket exclusion is that it "believes that certain programs under other Federal environmental laws adequately assess and effectively manage the risks for the covered exposure pathways." As the Agency explains, "[t]he provisions of various EPA-administered environmental statutes and their implementing regulations represent the judgment of Congress and the Administrator, respectively, as to the degree of health and environmental risk reduction that is sufficient under the various environmental statutes." Since the laws cited by EPA potentially apply to all releases into the environment, the effect of EPA's approach would be to remove environmental exposure pathways in their entirety from the TSCA risk evaluation process. This extreme approach is without any basis in the text of the law and will defeat the central purpose of TSCA reform – to conduct comprehensive risk evaluations on ubiquitous chemicals that examine the impacts on health and the environment of all of the diverse pathways and modes of release that may result in harm. Environmental media – air, surface water, groundwater, drinking water and waste – are known and pervasive sources of exposure for many substances. Any risk evaluation that fails to account for their contribution to total exposure will provide the public with a misleading and incomplete account of their potential to harm human health and fail to identify critical opportunities for risk reduction.	Y	N	N	N	N	N	N	N	N	N	N
467	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Policy, Exposure	2.2, 2.3	A. TSCA Risk Evaluations Must Examine Total Risk and Consider All Contributors to Exposure and Conditions of Use Risk evaluations under TSCA section 6(b)(4)(A) must determine "whether a chemical substance presents an unreasonable risk of injury to health or the environment." These evaluations must therefore examine the totality of risks presented by the substance, taking into account all contributors to exposure, including not just its presence in the workplace or consumer products but its releases into the environment. Indeed, under the plain language of the statute, EPA's focus expressly includes risks to the environment in addition to human health. "Environment" is defined in section 3(6) to include "air, water and land and the interrelationship which exists among and between air, water and land and all living things." If EPA excludes the chemical's presence in environmental media (air, water and soil) and the impacts on the environment of that presence on humans and other living things, then it cannot meet its obligation to determine environmental risks.	Y	N	N	N	N	N	N	N	N	N	N
468	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Policy, Exposure	2.2	Section 6(b)(4)(A) also provides that a risk evaluation must also determine the substance's risks under "the conditions of use." This broad term spans the entire life cycle of a chemical. It is defined under section 3(4) to mean "the circumstances . . . under which a chemical substance is intended, known or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of." The "circumstances" to which the definition applies clearly include air emissions and water discharges from industrial facilities as well as releases to environmental media during disposal. For EPA to exclude all such environmental releases from its risk evaluations would remove from the application of the law a large category of "conditions of use" that Congress directed EPA to address.7 Footnote: 7 As SCHF and its co-petitioners have argued in their brief in Safer Chemicals Healthy Families v. EPA, the statute gives EPA no discretion to exclude any conditions of use from risk evaluations, let alone the broad universe of environmental releases that occur during manufacture, processing, use, distribution in commerce and disposal of a chemical substance.	Y	N	N	N	N	N	N	N	N	N	N
469	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy, Exposure	2.3	B. Environmental Exposure Pathways Are Central to Chemical Prioritization, Risk Evaluation and Regulation under Section 6 of TSCA Other provisions in section 6 confirm the need to consider environmental releases as part of chemical prioritization and risk evaluation. For example, storage near significant sources of drinking water is a factor that EPA must examine in its process for designating chemicals as high- or low-priority under section 6(b)(1)(A). Similarly, under both this provision and section 6(b)(2)(D), chemicals with significant potential for persistence, bioaccumulation and toxicity (PBTs) must receive preference in the selection of substances for high-priority listing. PBTs are of concern because of their presence in environmental media and potential to concentrate in animals and humans as they are distributed in air, water and soil taken up the food chain. If EPA does not consider environmental release pathways of PBTs in evaluating their risks, it would be pointless to designate them as high-priority since the ensuing evaluation could not meaningfully address the contribution of environmental exposure pathways to total risk.	Y	N	N	N	N	N	N	N	N	N	N
470	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy, Exposure	2.2, 2.3	Paralleling the expansive definition of "conditions of use," the regulatory authorities in section 6(a) of the law empower EPA to take a broad array of actions to restrict chemical exposures and releases in order to eliminate unreasonable risks to health and the environment. Under the original law, EPA in fact used section 6(a) on a number of occasions to curtail environmental releases of toxic chemicals.8 Indeed, section 6(a)(6)(A) authorizes EPA to impose a "requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes." The authority to regulate disposal (a broad concept that can include virtually any release of wastes into air, water or land) would be meaningless if EPA did not use risk evaluations under section 6(b) to identify disposal activities that present an unreasonable risk of injury and are subject to restriction under section 6(a). Footnote: 8 Of the 6 existing chemicals EPA regulated under section 6 under the original law, the prevention of environmental releases was the basis for three of these regulatory actions. In 1978, EPA banned nonessential uses of fully halogenated chlorofluoroalkanes as propellants in aerosol spray containers because of concerns that these chemicals were destroying the upper atmosphere's ozone layer. In 1980, EPA promulgated a rule prohibiting Vertac Chemical Company and others from removing for disposal certain wastes containing 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) stored at Vertac's Jacksonville, Arkansas, facility. The rule also required any persons planning to dispose of TCCD contaminated wastes to notify EPA 60 days before their intended disposal. In 1994, EPA promulgated a rule to eliminate emissions of hexavalent chromium from comfort cooling towers.	Y	N	N	N	N	N	N	N	N	N	N

471	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	C. TSCA Legislative History Demonstrates that the Law Was Intended to Address Environmental Releases that May Be Within the Purview of Other Laws If Congress had intended a blanket exemption for environmental releases from risk evaluations under section 6(b) and regulation under section 6(a), it surely would have said so explicitly given the farreaching impact of such an exemption. Not only is there no such exemption in the law, but its legislative history and structure demonstrate that Congress intended TSCA to provide a comprehensive framework for identifying and managing chemical risks, including those that derive from environmental exposure pathways and could be addressed under other environmental laws.	Y	N	N	N	N	N	N	N	N	N	N
472	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	The comprehensive scope of TSCA was underscored in the legislative history of the original law. Congress recognized that then-existing environmental laws were "clearly inadequate" to address the "serious risks of harm" to public health from toxic chemicals. H.R. Rep. No. 94-1341, at 7 (1976); see S. Rep. No. 94-698, at 3 ("[W]e have become literally surrounded by a manmade chemical environment. … [T]oo frequently, we have discovered that certain of these chemicals present lethal health and environmental dangers."). While other federal environmental laws focused on specific media, such as air or water, none gave EPA authority to "look comprehensively" at the hazards of a chemical "in total." S. Rep. No. 94-698, at 2. Congress designed TSCA to fill these "regulatory gaps," S. Rep. No. 94-698, at 1, through a comprehensive approach to chemical risk management that considered "the full extent of human or environmental exposure," H.R. Rep. No. 94-1341, at 6. In amending TSCA in 2016, Congress sought to promote "effective implementation" of the 1976 law's objectives. See S. Rep. No. 114-67, 114th Cong., 1st Sess. (2015) at 2. At the time it strengthened TSCA, Congress affirmed that the intent of the original law—to give EPA "authority to look at the hazards [of chemicals] in total," S. Rep. No. 94-698, at 2—remained "intact." S. Rep. No. 114-67, at 7. Indeed, in a statement accompanying the law's passage, its Senate Democratic sponsors underscored that, with the expanded authorities conferred by Congress, TSCA should not be "construed as a 'gap filler' statutory authority of last resort" but "as the primary statute for the regulation of toxic substances." Excluding all pathways of chemical exposure through air, water and soil from risk evaluations would be directly contrary to these Congressional expectations.	Y	N	N	N	N	N	N	N	N	N	N
473	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	D. TSCA Section 9(b) Provides that EPA Must Decide Whether TSCA or Another Law is the Best Vehicle for Risk Management Only After Evaluating the Risks of a Chemical's Environmental Releases under TSCA In the 1976 law, Congress recognized the need to coordinate use of TSCA with implementation of other environmental laws. However, it chose to do so not by excluding environmental releases from the purview of TSCA – the approach EPA is pursuing now. Instead, it established a framework for determining, on a case-by-case basis, whether the risks of particular chemicals are best addressed under these laws or under TSCA. Thus, section 9(b)(1) of TSCA provides that EPA may use TSCA regulatory authorities if it "determines, in [its] discretion, that it is in the public interest to protect against [a particular] risk by action taken under this Act" but should use other environmental laws if it determines that "a risk to health or the environment . . . could be reduced to a sufficient extent by actions taken under" these laws.	Y	N	N	N	N	N	N	N	N	N	N
474	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	In 2016, Congress underscored the chemical-specific focus of this analysis by revising section 9(b)(2) so that, in deciding whether to regulate under TSCA or another law, EPA must "consider . . . all relevant aspects of the risk" in question and make a "comparison of the estimated costs and efficiencies" of addressing the risk under TSCA and other laws. Commenting on this language, the law's Senate Democratic sponsors explained that it allowed EPA to regulate under other laws in lieu of TSCA only where the "Administrator has already determined that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by additional actions taken under other EPA authorities." This approach presupposes that EPA has already used the TSCA risk evaluation process to identify the risks of a chemical and the exposure pathways contributing to those risks and thus has an informed basis to determine whether they "could be eliminated or reduced to a sufficient extent" under another law. If EPA has not examined the specific pathways of environmental exposure and their contribution to total risk under TSCA, then it cannot conduct the analysis that section 9(b) requires because it will be unable to evaluate the relative strengths of using TSCA or another law to eliminate the risk. By presuming that other laws are always superior to TSCA in identifying and reducing the risks of chemicals in environmental media, EPA's blanket exclusion of environmental releases thus turns section 9(b) on its head.	Y	N	N	N	N	N	N	N	N	N	N
475	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	E. Contrary to EPA, There is No Basis to Conclude that Other Environmental Laws are Equivalent in Scope and Protectiveness to TSCA EPA's position that other environmental laws should displace TSCA risk evaluations for all chemicals arbitrarily assumes that these laws provide equivalent protection of public health and the environment and that there is no added benefit in addressing environmental pathways of exposure under TSCA. But in reality these other laws vary greatly in the degree of protection they afford against chemical risks and the extent of their application to unsafe chemicals. These limitations are precisely why Congress gave EPA comprehensive authority over chemical risks under TSCA in 1976 and strengthened that authority in 2016.	Y	N	N	N	N	N	N	N	N	N	N
476	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Policy	N/A	The 2016 TSCA amendments establish a risk-basic framework for EPA's decisions on chemical safety and set a high standard of protection of health and the environment. Under section 6(b)(4)(A), TSCA risk evaluations must: "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors" (emphasis added). This determination must be for both the general population and "potentially exposed or susceptible subpopulations." Once an unreasonable risk is identified, TSCA section 6(c)(1) requires EPA to issue a rule under section 6(a) to address the risk. Section 6(a), in turn, directs that this rule must restrict the chemical "to the extent necessary so that the chemical substance no longer presents such risk" – again assuring protection of potentially exposed or susceptible subpopulations. As EPA has recognized, it cannot lower this level of protection based on consideration of costs and benefits. Although the rule must be accompanied by an economic analysis, the restrictions it imposes must be sufficient to eliminate the unreasonable risk identified in the evaluation. Indeed, the 2016 TSCA revisions were explicitly designed to remove the cost-benefit framework required under the old law because it had impeded meaningful regulation of unsafe chemicals.	Y	N	N	N	N	N	N	N	N	N	N
477	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Policy	N/A	TSCA's strict risk-based framework for chemical risk management is not mirrored in most environmental laws that govern releases to air, water and soil and disposal of waste. For example, the standard-setting process to establish discharge limits for chemical and other pollutants under the Clean Water Act (CWA) is technology-based and does not allow for consideration of risk. The same is true of several provisions of the Clean Air Act (CAA) that regulate emissions from new and modified stationary sources of pollution and mobile sources. In addition, the primary CAA mechanism for controlling industrial emissions of air toxics calls for EPA to set standards requiring Maximum Achievable Control Technology (MACT), an approach that does not take into account risks to health, although any "residual risks" can be addressed in a second stage of rulemaking.	Y	N	N	N	N	N	N	N	N	N	N
478	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Policy	N/A	Even statutes that do allow for consideration of risks also direct EPA to weigh cost and other economic factors. The Safe Drinking Water Act (SDWA), for example, requires cost-benefit balancing in setting limits for drinking water contaminants, the very approach rejected in the 2016 TSCA amendments. The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), which governs the remediation of contaminated sites, focuses on health protection but also directs EPA to take into account costs and technical achievability.17 And importantly, most of these laws do not include TSCA's explicit protections for potentially exposed or susceptible subpopulations at higher risk than the general population. In short, the bulk of EPA-implemented environmental laws lack the high level of protectiveness and exclusive focus on eliminating unreasonable risks that Congress demanded in its recent TSCA revisions.	Y	N	N	N	N	N	N	N	N	N	N

479	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Policy	N/A	Equally important, in comparison to TSCA, the scope of regulation under other federal environmental laws is limited: these laws generally apply to only a subset of the substances that may present risks to health or the environment and only a subset of the facilities whose environmental releases contribute to these risks. For example, air toxics emission requirements in the CAA only address 189 Hazardous Air Pollutants (HAPs) designated by Congress in the 1990 CAA amendments and only large industrial emitters that meet the CAA definition of "major source" are subject to emission limits. Similarly, CERCLA cleanups encompass a statutory list of hazardous substances and disposal requirements under the Resource Recovery and Conservation Act (RCRA) only apply to those wastes that EPA has designated as "hazardous." Industrial discharge limits under the CWA only apply to regulated "toxic" pollutants and the CWA's water quality framework involves a complex mix of state and federal standards that vary across regions, may not address all pollutants that threaten human health and often do not result in uniform levels of protection. These basic gaps in coverage are painfully evident as EPA and states struggle to address widespread contamination and threats of harm to human health resulting from the extensive use and environmental release of Per- and polyfluoroalkyl substances (PFAS). Despite their significant risks, PFAS chemicals are not regulated as HAPs under the CAA, drinking water contaminants under the SDWA, hazardous substances under CERCLA or toxic pollutants under the CWA.	Y	N	N	N	N	N	N	N	N	N	N
480	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	While EPA may have authority to expand the reach of its environmental laws to include previously unregulated toxics, it cannot do so without first evaluating the risks of these chemicals. With limited exceptions, however, EPA has no obligation under its environmental laws to assess the risks of unregulated chemicals or even to update its understanding of the hazard and exposure profile of those substances that are regulated. In practice, moreover, EPA's other regulatory programs have limited resources and many competing priorities, including those required by specific statutory provisions and/or court orders. Thus, there is little likelihood that previously unaddressed chemical risks will be evaluated by these programs. Indeed, many existing environmental standards are decades old and no longer reflect the best available science but EPA's environmental media programs lack the bandwidth and inclination to update them based on current understanding of risks to human health and the environment. For all these reasons, by precluding the use of TSCA to determine the health and environmental impacts of chemical releases to air, water and soil, EPA is effectively closing the door to any meaningful evaluation of these impacts – and, thus, to the use of TSCA or other laws to restrict those releases that are found to be unsafe.	Y	N	N	N	N	N	N	N	N	N	N
481	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	In sum, exclusion of all environmental releases from TSCA risk evaluations is contrary to the wording, intent and purposes of the law and will inevitably mean that serious threats to health and the environmental are neither identified nor addressed.	Y	N	N	N	N	N	N	N	N	N	N
482	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure	2.6	III. There is No Legal or Technical Justification for Excluding General Population Exposure from EPA's Risk Evaluations Several of the problem formulations indicate that EPA will not evaluate the risks of general population exposure. As stated in the PERC problem formulation: EPA does not plan to consider and analyze general population exposures in the risk evaluation for PERC. EPA has determined that the existing regulatory programs and associated analytical processes have addressed or are in the process of addressing potential risks of TCE that may be present in various media pathways (e.g., air, water, land) for the general population. For these cases, EPA believes that the TSCA risk evaluation should focus not on those exposure pathways, but rather on exposure pathways associated with TSCA uses that are not subject to those regulatory processes.	Y	N	N	Y	N	N	N	N	N	N	N
483	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Exposure	N/A	This approach is unjustified for the reasons discussed above. If the presence of a chemical in environmental media – and therefore exposure to the chemical by the general population – is attributable to its "conditions of use", there is no basis for excluding this background level of exposure from EPA's risk evaluation. The claim that this exclusion is justified because "existing regulatory" programs apply to environmental releases is unsupported by the law: in accordance with section 9(b), EPA must first determine the risk resulting from environmental releases through a TSCA risk evaluation and then determine whether the risk is best addressed under TSCA or other EPA-administered environmental laws.	Y	N	N	N	N	N	N	N	N	N	N
484	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Exposure	N/A	The goal of risk evaluations under section 6(b)(4)(A) is to determine the risks presented by a chemical as a whole, not the risks of individual uses and pathways in isolation. Moreover, section 6(b)(4)(F) directs EPA to take into account "the likely duration, intensity, frequency and number of exposures under the conditions of use of the chemical substance" and to "integrate and assess available information on hazards and exposures for the conditions of use." This integrating analysis cannot be performed if some pathways of exposure are excluded simply because they involve environmental media and could be subject to other laws. As the House Report for original TSCA emphasized, "[i]ntelligent standards for regulating exposures to a chemical in the workplace, the home or elsewhere in the environment cannot be set unless the full extent of human or environmental exposure is considered."	Y	N	N	N	N	N	N	N	N	N	N
485	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure	N/A	The background levels of a chemical in the environment may present an unreasonable risk to the general population in their own right or they may add to other sources of exposure to present an overall risk to specific populations that is unreasonable. In either event, EPA cannot discharge its obligations under the law unless it determines and takes into account the background levels of a chemical to which the general population is exposed.	Y	N	N	N	N	N	N	N	N	N	N
486	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, PESS, Exposure	N/A	IV. EPA's Continues to Fail to Explain What Methodology It Will Use to Account for Multiple Exposure Pathways that Increase Overall Risk The law's clear requirements for evaluating and protecting against risks to "potentially exposed or susceptible subpopulations" further underscore EPA's obligation to consider all contributors to exposure and risk, including a chemical's presence in environmental media. In order to determine whether a subpopulation may be at greater risk because it has greater exposure than the general population, the Agency must first quantify general population exposure and then determine how this exposure is increased because of exposures in the workplace, through products, as a result of environmental releases or because of other pathways that affect a particular subpopulation. To protect these subpopulations, EPA's focus must be on whether the total risk they face, considering all sources of exposure, is unreasonable. If one or more contributors to exposure are ignored, groups who are at greater risk than the general population because of multiple exposure pathways will be inadequately protected.	Y	N	N	N	N	N	N	N	N	N	N
487	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure, PESS	N/A	Recognizing the need to account for the impact of multiple sources of exposure, TSCA section 6(b)(4)(F)(ii) requires risk evaluations to describe whether aggregate or sentinel exposures to a chemical were considered and the basis for that consideration. To properly apply either or both of these approaches in a risk evaluation, EPA must determine in advance what methodology it will employ and then incorporate it in the risk evaluation design in sufficient detail to describe the key data sources it will use to assess exposure and how they will be used. EPA has not done this. Disappointingly, neither the scoping documents nor the problem formulations shed any light on how EPA risk evaluations will account for multiple pathways of exposure by the general population or subpopulations. Instead, it appears that EPA will examine each source of exposure in isolation and will not consider either the combined effect of multiple exposures or the contribution of environmental releases to overall exposure and risk. This is a violation of TSCA.	Y	N	N	N	N	N	N	N	N	N	N

488	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure	Executive Summary	V. Ongoing Use and Disposal of Chemical Products that are No Longer Being Manufactured Fall Within the TSCA Definition of "Conditions of Use" and Cannot Be Excluded from Risk Evaluations Among the 10 chemicals are substances, such as asbestos and HBCD, that contribute to ongoing exposure and risk as a result of historical manufacturing and processing activities that have been discontinued. In many cases, the current and foreseeable risks associated with these activities are significant. Nonetheless, the problem formulations, like the scoping documents, take the position that they are outside the scope of risk evaluations. As stated in EPA'S asbestos problem formulation: "In the case of asbestos, legacy uses, associated disposals, and legacy disposals will be excluded from the problem formulation and risk evaluation, as they were in the Scope document. These include asbestos containing materials that remain in older buildings or are part of older products but for which manufacture, processing and distribution in commerce are not currently intended, known or reasonably foreseen. EPA is excluding these activities because EPA generally interprets the mandates under section TSCA § 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacture, processing or distribution is intended, known to be occurring, or reasonably foreseen, rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of conditions of use in that context."	Y	N	N	N	N	Y	N	N	N	N	Y
489	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	2.2	EPA is incorrectly interpreting the provisions of LCSA. The definition of "conditions of use" in section 3(4) includes the "circumstances . . . under which a chemical substance is . . . known or reasonably foreseen to be . . . used or disposed of." Where a chemical is performing an ongoing in situ function as a result of previous manufacturing and processing activity, that function comprises a current "use" of the chemical that is "known" to be occurring.26 Footnote: 26 SCHF and its co-petitioners are challenging EPA's position that ongoing use and disposal of discontinued products are not TSCA "conditions of use" in Safer Chemicals Healthy Families v. EPA, 17-72260 (9th Cir.) In addition to being used and disposed of, legacy products that perform functions in the built environment can be considered "distributed in commerce" as this term is defined in TSCA section 3(5). The definition includes "to hold, or the holding of, the substance, mixture or article after its introduction in commerce" – language that plainly applies to in situ products. Likewise, the definition includes the "introduction or delivery for introduction into commerce" of the substance, mixture or article. This description would apply to legacy products that are repurposed or sold for recycling.	Y	N	N	N	N	N	N	N	N	N	N
490	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Exposure, Human Health	2.2, 2.3	For example, although asbestos may no longer be sold as insulation, the asbestos insulation installed in millions of US buildings continues to perform insulating functions and thus is a current ongoing "use" of asbestos. Installed asbestos-containing building materials (ACBMs) represent one of the largest sources of asbestos accessible to the general public in the US, and the largest asbestos-exposed population consists of people who occupy buildings and homes with ACBMs. Maintenance and construction activities involving ACBMs are also frequent and widespread and account for the largest present-day increase in mesothelioma illness and death in the US.	N	N	N	N	N	N	N	N	N	N	Y
491	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Exposure	2.2, 2.3	Similarly, the Healthy Building Network estimates there are 66 million- 132 million pounds (30,000-60,000 metric tons) of HBCD in insulation in existing buildings. These ongoing insulation uses are and will continue to be critical sources of ongoing exposures. HBCD is also present in cars and furniture as a flame retardant and its use in these long-lived consumer articles will contribute to ongoing exposures for years to come.29 Footnote: 29 It is unclear whether EPA intends to exclude installed HBCD-containing building and construction materials from its risk evaluation. The problem formulation states that the evaluation will address "commercial/consumer use" of "building/construction materials" but this could be interpreted to apply to materials that are available for use in ongoing construction projects and not those already installed. See Problem Formulation for Cyclic Aliphatic Bromides Cluster (HBCD) (May 2018) at 29.	N	N	N	N	N	Y	N	N	N	N	N
492	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Exposure	2.2, 2.3	Equally important, the disposal of building materials or consumer products containing asbestos or HBCD is an ongoing occurrence as buildings are torn down or remodeled and cars and furniture are replaced. Thus, the resulting releases into the environment and communities comprise a "circumstance . . . under which [these chemicals] are . . . known or reasonably foreseen to be . . . disposed of." As "conditions of use" within the TSCA definition, these activities and the risks they present are likewise required to be addressed in risk evaluations under section 6(b). For both chemicals, the immediate and long-term exposures associated with disposal of in situ building materials and products are likely to be widespread and significant well into the future.30 Footnote: 30 EPA also excludes disposal from the asbestos and HBCD risk evaluations based on its overall determination that the release of chemicals to environmental media should not be addressed under TSCA. Oddly, disposal of HBCD construction and demolition waste is listed as a condition of use EPA plans to address in one part of its problem formulation (page 29) but then identified as an exposure pathway that will not be considered later in the same document (page 52).	N	N	N	N	N	Y	N	N	N	N	N
493	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure	2.2, 2.3	To exclude from risk evaluations ongoing and future exposures from in situ uses of discontinued products would create a sizable gap in the life-cycle assessments of risk that Congress directed EPA to conduct under the new law. This would deprive the public, scientists and regulators of a comprehensive picture of one of the largest sources of continuing and future risk. Since in situ sources of exposure form a critical component of the background levels of asbestos and other chemicals to which the general population is exposed, EPA's assessment of risks to particular subpopulations from more specific exposure pathways would also be incomplete and understated.	Y	N	N	N	N	N	N	N	N	N	Y
494	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy, Exposure	2.2, 2.3	In addition, decision-makers would be unable to reduce ongoing exposures and impose safeguards against unsafe use and disposal and "legacy" products because they would lack a meaningful risk evaluation to inform these actions. Just as TSCA provides authority to evaluate the risks associated with ongoing exposures from discontinued activities, so it gives EPA the authority under section 6(a) to reduce these risks, yet the Agency would be stymied by the absence of a risk evaluation that provides a basis for such regulation.31 Footnote: 31 For some chemicals like lead and asbestos, other laws administered by EPA address handling and disposal of in situ materials and the Agency may be able to refer the findings of its risk evaluations to the programs implementing these laws under TSCA section 9(b) in lieu of further regulation under section 6. However, there are no existing laws that address ongoing exposure from use and disposal of discontinued products containing HBCD, perfluorinated chemicals and other substances and therefore the availability of the protections afforded under section 6 of TSCA may be critical to addressing their risks. Obviously, if these risks are not identified and evaluated under TSCA section 6(b), there will be no basis for reduction them through regulation under section 6(a).	Y	N	N	N	N	Y	N	N	N	N	Y
495	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure	2.2, 2.3	In short, EPA must characterize and assess ongoing exposures from the use and disposal of discontinued products and determine the risks they present as part of its risk evaluations on the initial 10 chemicals. Its continuing failure to do so is a clear violation of TSCA.	Y	N	N	N	N	N	N	N	N	N	N
496	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	2.2	VI. Uses Discontinued under the Threat of Regulatory Action Fall Within the TSCA Definition of "Conditions or Use" and Must be Addressed in TSCA Risk Evaluations A number of the problem formulations indicate that certain chemical uses have been discontinued and therefore will not be addressed in the risk evaluation for that chemical.	Y	N	N	N	N	N	N	N	N	N	N

497	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	2.2	The problem formulation for HBCD illustrates this approach. Based on representations by industry, EPA asserts that HBCD use in the production of flame retardants, EPS resins, high impact polystyrene, XPS master batch, motor vehicle upholstery, consumer textiles, and military, institutional and aviation textile applications has ceased. According to EPA, these uses are no longer "intended, known or reasonably foreseen" and therefore do not comprise TSCA "conditions of use" that will be addressed in the HBCD risk evaluation. EPA also indicates that because HBCD is no longer being manufactured in the US, domestic production will likewise not be addressed.	N	N	N	N	N	Y	N	N	N	N	N
498	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	2.2	EPA has not disclosed the industry communications it is relying on but it appears they are informal and non-binding and have not been verified by the Agency. Nor has EPA indicated that it has contacted all HBCD producers and users to confirm that the uses in question have been fully eliminated. Thus, there is no assurance that these HBCD uses no longer exist and, if so, will not be revived in the future. Indeed, the most likely explanation for the phase-out of previously well-established HBCD uses is the regulatory and public scrutiny HBCD has received, a consideration that could wane in importance in the future, particularly if the risks presented by these uses are not evaluated or restricted by EPA.	N	N	N	N	N	Y	N	N	N	N	N
499	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Epolicy	2.2	EPA has also narrowed the scope of the asbestos risk evaluation by excluding now discontinued but historically significant asbestos-containing products and failing to address mining of asbestos in the US. Instead, EPA has proposed a significant new use rule (SNUR) so that it is notified of the reintroduction of discontinued products before it occurs. However, while EPA has the ability to ban or restrict a new use after receiving notification under a SNUR, the SNUR does not itself comprise a finding of unreasonable risk nor does it provide any assurance that the use would be regulated once the Agency receives a significant new use notice (SNUN). With the exclusion of discontinued asbestos uses, the EPA risk evaluation will be limited to the small number of asbestos products that remain in commerce, providing a grossly incomplete picture of the threat to health from past and potential future uses of asbestos.	N	N	N	N	N	N	N	N	N	N	Y
500	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	2.2	We disagree with EPA that discontinuance of a previously widespread use necessarily places it beyond the reach of section 6 risk evaluation and management authorities. EPA provides no justification for its assertion that the TSCA definition of "conditions of use" does not apply to such uses. As defined in section 3(4), this term includes not simply intended or known uses but the "circumstances under which a chemical substance is . . . reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of." It is clearly "reasonably foreseen" that long-standing and significant uses of a chemical that have been phased out may re-enter commerce in the absence of any legal restriction. Moreover, section 6(a) provides that EPA must regulate a chemical where "manufacture, processing, distribution in commerce, use or disposal" presents an unreasonable risk but does not stipulate that these activities must be currently occurring to warrant restriction. Indeed, the purpose of section 6(a) rules – to impose the measures "necessary so that the chemical substance no longer presents [an unreasonable] risk" – is equally applicable to ongoing commercial activities and to historical uses that could resume and require restrictions so they do not cause harm to health and the environment.	Y	N	N	N	N	N	N	N	N	N	N
501	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	Although the 2016 TSCA amendments removed the phrase "will present" from section 6(a), the statement of Democratic sponsors at the time of enactment makes clear that EPA retained its authority to address anticipated future risks: "Existing TSCA as in effect before the date of enactment of Frank R Lautenberg Chemical Safety for the 21st Century Act includes the authority, contained in several sections (see, for example, section 6(a)), for EPA to take regulatory actions related to chemical substances or mixtures if it determines that the chemical substance or mixture 'presents or will present' an unreasonable risk to health or the environment. The Frank R. Lautenberg Chemical Safety for the 21st Century Act includes language that removes all instances of 'will present' from existing TSCA and the amendments thereto. This does not reflect an intent on the part of Congressional negotiators to remove EPA's authority to consider future or reasonably anticipated risks in evaluating whether a chemical substance or mixture presents an unreasonable risk to health or the environment. In fact, a new definition added to TSCA explicitly provides such authority and a mandate for EPA to consider conditions of use that are not currently known or intended but can be anticipated to occur . . . "	Y	N	N	N	N	N	N	N	N	N	N
502	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	The goals of TSCA would be defeated if manufacturers of unsafe chemicals could avoid scrutiny simply by ceasing production for specific uses before EPA completes a risk evaluation of those uses and then later re-entering the marketplace free from any restriction or determination of risk. This scenario is particularly troubling where the product phase-out is in response to agency risk concerns and intended to avoid the consequences of an adverse risk finding and subsequent regulatory action. In these cases, the best interpretation of TSCA is to treat the possible reintroduction of a discontinued use as "reasonably anticipated," to address that use in the risk evaluation and to then ban or restrict it permanently under section 6(a) if it is determined to present an unreasonable risk.	Y	N	N	N	N	N	N	N	N	N	N
503	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	We do not believe a SNUR is an adequate substitute for evaluation and regulation of a discontinued chemical use under section 6. SNURs are fundamentally notification requirements and do not themselves require an assessment or determination of risk. The activities they define as "significant new uses" are not prohibited: companies seeking to conduct these activities must notify EPA at least 90 days before initiating them. While the Agency must review the new use and ban or restrict it under sections 5(e) or 5(f) upon determining that the use does or may present an unreasonable risk, the Agency may or may not choose to take these actions. Thus, the door will not be closed to reintroduction of the use. Moreover, EPA's review of a SNUN and decision to regulate the new use lack the elements of openness and accountability that apply during section 6 risk evaluations and rulemakings. Thus, these decisions will receive limited public and judicial review.	Y	N	N	N	N	N	N	N	N	N	N
504	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	A comprehensive risk evaluation under section 6, by contrast, enables the Agency to make a definitive risk determination for plausible future risk scenarios in a transparent process that provides clarity to industry and the public and closes the door to the resumption of unsafe uses. If there is a role for a SNUR, it is to perform the limited stop-gap function of assuring that EPA is notified of significant changes in use while its risk evaluation and follow-up rulemaking are underway so that these uses are not reestablished in the marketplace before EPA has addressed their risks under section 6 and restricted them if warranted.	Y	N	N	N	N	N	N	N	N	N	N

505	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	VII. EPA Should Not Make Determinations of Unreasonable Risk for Endpoints that Lack Adequate Information and Should Use its Section 4 Authorities to Require Industry to Fill These Data gaps Our groups have repeatedly called for EPA to identify data gaps that limit its ability to reach definitive conclusions about the health and environmental effects of the 10 chemicals. We have urged EPA to take steps to fill these data gaps early in the risk evaluation process using its expanded TSCA information development authorities so that sufficient information is available for an informed evaluation. EPA itself has emphasized the need for comprehensive data on hazard and exposure before it initiates evaluations although it has backed away from a systematic information collection process at the pre-prioritization stage for risk evaluation candidates.36 Basing risk evaluations on adequate data is not only necessary to meet EPA's obligation under section 26(k) to consider all "reasonably available information" but furthers section 2(b)(2), which declares that "[i]t is the policy of the United States" that "adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment." Footnote: 36 In the discussion paper EPA prepared for its December 11, 2017 public meeting on prioritization, EPA stated that: Prior to designating a chemical as a high-priority for risk evaluation, it is important for EPA to ensure the reasonably available information is sufficient to conduct a scientifically robust risk evaluation. In many cases, EPA believes it would be difficult to require the development of necessary chemical substance information, evaluate that information, and incorporate that information into analyses and decisions within the statutory timeframes associated with the prioritization and risk evaluation processes. Therefore, it will be useful for EPA to identify information needs and determine whether any of these needs should be addressed before initiating the prioritization process. DISCUSSION DOCUMENT: Possible Approaches and Tools for identifying Possible Candidate Chemicals for Prioritization at 7. Despite this recognition, EPA's final prioritization framework rule deleted a pre-prioritization process that would have expressly provided a process for identifying and filling data gaps before risk evaluations are initiated. Procedures for Prioritization of Chemicals for Risk Evaluation under the Toxic Substances Control Act. 82 Fed. Reg. 33753 (July 20, 2017).	Y	N	N	N	N	N	N	N	N	N	N
506	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	It is therefore disappointing that the problem formulations, like the earlier scoping documents, make minimal efforts to identify significant data gaps for the 10 chemicals, to set in motion development of additional information, and to address how these data gaps will impact the conclusions reached in the risk evaluations. Indeed, EPA seems ready to find that substances do not present an unreasonable risk of injury even where available data are lacking entirely or are insufficient under Agency guidelines to determine that a substance lacks adverse effects.37 Footnote: 37 The EPA responses to comments on the scoping documents indicate that: "when OPPT does find existing data are not adequate, OPPT will use all available authorities to fill data gaps necessary to conduct fit-for-purpose assessments." This is not, however, the approach reflected in the problem formulations.	Y	N	N	N	N	N	N	N	N	N	N
507	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Human Health	N/A	Pigment violet 29 is a case in point. The problem formulation for this substance indicates that, based on the absence of significant evidence of hazard, EPA "expects to be able to reach conclusions about particular conditions of use, hazards, or exposure pathways without further analysis." Yet nowhere does EPA address whether it has sufficient information to reach such conclusions for major health endpoints. EPA's Design for the Environment (now known as Safer Choice) Program and risk evaluation guidelines and REACH requirements in the EU identify the studies deemed necessary for an informed risk evaluation. The database for pigment violet 29 is deficient when measured against these authoritative sources. Illustrating these deficiencies, the table below compares the test data available on pigment violet 29 with the requirements for a DfE/Safer Choice human health hazard trait assessment.39 [p. 20, Table depicts DfE Hazard Trait and Empirical Available Data for PV29. Data were available for acute mammalian toxicity, skin sensitization, eye and skin irritation/corrosivity, mutagenicity/genotoxicity, and reproductive and developmental toxicity. No data were available for respiratory sensitization, carcinogenicity, developmental neurotoxicity, neurotoxicity, repeated dose toxicity, or endocrine activity.] Footnote: 39 SCHF is grateful to scientists at the University of California San Francisco for preparing this table, which is included in comments on the problem formulations filed on behalf of a group of academics, scientists, and clinicians.	N	N	N	N	Y	N	N	N	N	N	N
508	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Human Health	2.4.2	Thus, EPA could not reach scientifically defensible conclusions that pigment violet 29 lacks the potential to cause carcinogenicity, reproductive and developmental toxicity, developmental neurotoxicity, neurotoxicity, repeated dose toxicity or endocrine effects.	N	N	N	N	Y	N	N	N	N	N	N
509	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Human Health	N/A	Pigment violet 29 is not the only one of the 10 chemicals with significant data gaps. 1,4-dioxane, MC, PERC and TCE also lack data for important end-points:	N	N	Y	Y	Y	N	N	Y	N	Y	N
510	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Human Health	2.4.2	1,4 Dioxane. For this chemical, there is little or no information on the potential for developmental toxicity or developmental neurotoxicity. This is especially problematic given that the chemical is a well-known neurotoxic agent. This critical data gap was identified by ATSDR in its 2012 Tox Profile.	N	N	Y	N	N	N	N	N	N	N	N
511	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Human Health	2.4.2	MC. MC is a known human neurotoxicant, associated with depression of the central nervous system, and severe dose-dependent neurotoxic effects including headaches, slowed reaction time, decreased alertness, impaired movements, loss of consciousness, coma, seizures, and death. (It has been shown in animal studies to cross the placenta, and in humans it has been detected in breast milk.) Yet, the chemical has not been adequately tested for developmental neurotoxicity. This is especially alarming given the widespread use and population exposure to this deadly neurotoxic chemical. Chemicals that are neurotoxic should be presumed to be developmentally neurotoxic. That is, compared with adult exposures, they are much more damaging and at much lower levels when exposures take place during early fetal development. The failure to test and appropriately regulate these chemicals has led to debilitating neurodevelopmental disorders such as autism, learning deficits, and behavioral problems – all with disastrous impacts on affected individuals, families, and society.	N	N	N	N	N	N	N	Y	N	N	N
512	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Human Health	2.4.2	PERC. This chemical is considered by EPA to be both neurotoxic and a developmental toxicant, yet it has never been tested for developmental neurotoxicity. This is a major data gap, given that developmental neurotoxic effects such as learning impairments and behavioral problems are often overlooked in routine tests such as the ones EPA considered, which focus on crude frank toxicity such as reduced body or organ weights, stillbirths and deaths (see Perc problem formulation, p. 52). Lead, mercury, and other developmental neurotoxic chemicals have all been shown to have virtually no safe level when exposures occur prenatally during critical windows of neurodevelopment. For this reason, the EPA pesticide office began requiring pesticide registrants to submit developmental neurotoxicity testing – which includes subtle but important endpoints like motor activity, learning and memory, and auditory startle response – for the organophosphates and other pesticides known to be neurotoxic. In an EPA fact sheet issued last month, EPA emphasizes why specific developmental neurotoxicity tests are important: • The developing nervous system can be particularly sensitive to exposure to environmental chemicals. • Less than 1% of chemicals in the environment have been fully evaluated for their potential to be developmental neurotoxicants, or their impact on the developing nervous system. • Due to a lack of data, it is not possible to understand the extent or potential contribution of environmental chemicals in neurodevelopmental disease, nor predict the potential developmental neurotoxicity risk for individual chemicals. The failure to address the risks of developmental neurotoxicity posed by PERC represents a serious data gap in EPA's assessment, particular for the low-dose risks.	N	N	N	Y	N	N	N	N	N	N	N

513	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Human Health	2.4.2	TCE. Trichloroethylene was evaluated well over a decade ago, in 2004, by the EU, which at the time identified the need for developmental neurotoxicity testing to be conducted for TCE: " The developmental toxicity of inhaled trichloroethylene at non-maternally toxic levels (up to 1,800 ppm) has been investigated in rats, mice and rabbits in conventional studies. No evidence of developmental toxicity was reported. In contrast, the results of a series of non-standard oral studies in rats raised some concerns about the potential for trichloroethylene to induce developmental neurotoxicity at dose levels in the range of 30-110 mg/kg/day. However, these studies were of limited scope and were considered not to provide sufficient basis on which to draw clear conclusions about the hazardous properties of trichloroethylene. To be able to draw clear conclusions regarding developmental neurotoxicity, further testing according to the draft OECD TG 426 Developmental Neurotoxicity guideline would be required."	N	N	N	N	N	N	N	N	N	Y	N
514	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Human Health	2.4.2	The 2011 IRIS assessment comes to similar conclusions, also identifying the potential for developmental neurotoxicity and noting this data gap: "In summary, an overall review of the weight of evidence in humans and experimental animals is suggestive of the potential for developmental toxicity with TCE exposure. A number of developmental outcomes have been observed in the animal toxicity and the epidemiological data, as discussed below. These include adverse fetal/birth outcomes including death (spontaneous abortion, perinatal death, pre- or post-implantation loss, resorptions), decreased growth (low birth weight, SGA [small for gestational age], IUGR [intrauterine growth restriction], decreased postnatal growth), and congenital malformations, in particular cardiac defects. Postnatal developmental outcomes include developmental neurotoxicity, developmental immunotoxicity, and childhood cancer."	N	N	N	N	N	N	N	N	N	Y	N
515	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Human Health	2.4.2	The TCE problem formulation identifies the risk of neurotoxicity and developmental toxicity separately, noting evidence from both human studies and animal studies, including psychomotor effects from TCE exposures. Yet, there is no study that specifically targets the sensitive and critical endpoint of developmental neurotoxicity. The failure to address the risks of developmental neurotoxicity posed by TCE represents a serious data gap in EPA's assessment, particular for the low-dose risks.	N	N	N	N	N	N	N	N	N	Y	N
516	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Policy, Human Health	2.4.2	In the face of material data gaps, an unqualified conclusion that a chemical does not "present an unreasonable risk of injury" to health could not be defended under TSCA and would misinform the public about the chemical's safety.51 Thus, EPA's risk evaluations should be explicit about the health and environmental end-points that lack adequate data and should exclude these end-points from its determinations of unreasonable risk. It should also use its TSCA authorities to require manufacturers to conduct testing to develop adequate data for a defensible risk evaluation so that future assessments can be informed by a comprehensive dataset. EPA's lack of interest in using section 4 of the law to generate data necessary for risk evaluation is deeply troubling in light of the clear intent of the 2016 TSCA amendment to provide the Agency with the tools to require more testing by industry to support priority setting and risk evaluations under section 6. Footnote: 51 EPA has recognized that "OPPT does not believe that absence of data equals no risk." EPA's Responses to Public Comments Received on the Scope Documents for the First Ten Chemicals for Risk Evaluation under TSCA (May 2018) at 13. However, the problem formulations suggest that the Agency is not applying this principle in its evaluations of individual chemicals.	Y	N	N	N	N	N	N	N	N	N	N
517	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	1	VIII. Where EPA Believes that Particular Conditions of Use Present De Minimis Risks, It Cannot Drop These Uses with no Additional Analysis, But Rather Must Explain and Document Why Their Risks Are Insignificant The problem formulations also indicate that EPA "expects to be able to reach conclusions about particular conditions of use, hazards or exposure pathways without further analysis" and will not further address them in its risk evaluations.52 For example, EPA indicates that it will devote no further attention to multiple uses of carbon tetrachloride (CTC) that it asserts pose only de minimis risks: • Because industrial, commercial, and consumer use of such products (solvents for cleaning/degreasing, adhesives/sealants, and paints/coatings) would present only de minimis exposure or otherwise insignificant risk, EPA has determined that these conditions of use do not warrant evaluation, and EPA does not expect to consider or evaluate these conditions of use or associated hazards or exposures in the risk evaluation for carbon tetrachloride. Footnote: 52 This statement apears in the Introduction to all of the Problem Formulations.	Y	N	N	N	N	N	Y	N	N	N	N
518	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	2.2, 2.4.2	Nowhere has EPA provided general criteria for determining levels of exposure or risk that are "insignificant" for purposes of TSCA risk evaluations. Nor has the Agency explained why it considers carbon tetrachloride-containing solvents with potential consumer, industrial and commercial exposure to be so inconsequential that they can be determined not to present "unreasonable risks" without any product-specific analysis of use and release scenarios.54 Since carbon tetrachloride is a carcinogen, even low concentrations cannot be assumed to be safe without some understanding of the conditions and levels of exposure. Moreover, even if the risk from a specific product is small in itself, multiple products and exposure pathways may result in aggregate levels of exposure that present significant risks to one or more worker or consumer subpopulations. As noted above, TSCA requires EPA to examine chemical risks holistically, taking into account all uses and pathways of exposure, and cannot summarily eliminate an entire class of products from consideration. EPA may have some latitude to devote greater effort to some exposure and risk scenarios than others, but this does not excuse ignoring particular conditions of use based on the unsubstantiated claim that they present de minimis risks. Footnote: 54 EPA's initial use summary found products with up to 2.5% CTC and SCHF's submission to EPA of publically available product information included products with 1% CTC. See Safer Chemicals, Healthy Families, Environmental Health Strategy Center, Healthy Building Network, Comments to the U.S. Environmental Protection Agency (EPA) on the Scope of its Risk Evaluation for the TSCA Work Plan Chemical: CARBON TETRACHLORIDE (CTC) CAS Reg. No. 56-23-5 (March 15, 2017). This information is not reflected in the problem formulation for CTC.	Y	N	N	N	N	N	Y	N	N	N	N
519	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	2.2	It is also troubling that, despite numerous critical comments, EPA continues to ignore the presence of 1,4-dioxane as an impurity in products on the ground that "contamination of industrial, commercial and consumer products are not intended conditions of use for 1,4-dioxane and will not be evaluated." EPA's position is legally unsupportable. Production of a chemical as a byproduct or impurity is plainly a "circumstance . . . under which a chemical substance . . . is known . . . to be manufactured" and thus falls squarely within the definition of "conditions of use" in section 3(4) of TSCA. There is no basis in this provision or other parts of the law for differentiating between manufacture as a byproduct/impurity and purposeful production and including the latter in a risk evaluation but excluding the former. In the case of 1,4-dioxane, EPA has made no effort to argue that byproduct/impurity production poses de minimis risks and such a position could not be defended given the evidence that 1,4-dioxane's detection in drinking water and groundwater is linked in part to its presence as a contaminant in products and waste streams released into the environment. Plainly, EPA must add 1,4-dioxane production as a byproduct and impurity to the scope of its risk evaluation.	Y	N	Y	N	N	N	N	N	N	N	N

520	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Human Health	N/A, 2.4.2	IX. EPA Cannot Drop Significant Hazards from Risk Evaluations The asbestos problem formulation provides another example of an EPA decision "not to further analyze" a potential source of risk. EPA has chosen to limit its asbestos evaluation to lung cancer and mesothelioma. Yet the asbestos scoping document is clear that several other cancers have been linked to asbestos: "Mortality studies of asbestos workers have revealed increases in cancer mortality at one or more sites other than the lung, the pleura or the peritoneum. Cancer of the larynx and ovary and gastrointestinal cancers, such as colorectal, pharynx and stomach, have been observed in populations exposed to various types of asbestos (IARC, 2012; NRC, 2006). Some studies have also noted excess deaths from, or reported cases of, cancers at other sites, such as the kidney and esophagus; however, the evidence is not consistent." Non-malignant diseases are also caused by asbestos, including asbestosis and asbestos-related pleural thickening.	N	N	N	N	N	N	N	N	N	N	Y
521	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Human Health	N/A, 2.4.2	The comprehensive approach to risk evaluations in TSCA requires EPA to address all known hazards of a chemical, particularly one whose dangers to human health are so serious and well documented. The law provides no basis for failing to evaluate documented adverse health effects, let alone effects of this severity and magnitude.	Y	N	N	N	N	N	N	N	N	N	N
522	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	X. EPA Should Not Revisit Definitive Findings in IRIS Assessments Unless There Are New Data That Inform EPA's Evaluation of the Weight of the Evidence Six of the 10 chemicals -- asbestos, TCE, MC, CTC, PERC and 1,4-dioxane -- have been assessed under the EPA Integrated Risk Information System (IRIS). The IRIS process is the Agency's authoritative mechanism for reviewing available studies, characterizing the health effects of chemicals and identifying concentrations below which these chemicals are not likely to cause adverse effects. IRIS assessments typically reflect years of work by EPA scientists, multiple rounds of public comment, inter and intraagency consultation, and extensive peer review, often by the Agency's independent Science Advisory Board (SAB) or the National Academy of Sciences (NAS). The IRIS program recently received a favorable review from the NAS.	Y	N	Y	Y	N	N	Y	Y	N	Y	Y
523	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	Where EPA is conducting a TSCA risk evaluation of a chemical that has already been assessed under IRIS, the conclusions of the IRIS assessment should be presumed to be applicable to the TSCA evaluation as a definitive statement by the Agency of the best available science. Reopening IRIS findings would harm the public by prolonging uncertainty on issues that have been addressed and resolved through an authoritative, transparent and inclusive EPA process. Like other Agency actions, IRIS assessments often give rise to differences of opinion and some stakeholders may be disappointed by the outcome. But this does not mean that EPA should reinvent the wheel and provide another bite at the apple on scientific determinations that have been made after thorough deliberation. To revisit IRIS findings would also be inefficient and resource-intensive at a time when the Agency is struggling with workforce and budget constraints and is straining to manage its TSCA workload.	Y	N	N	N	N	N	N	N	N	N	N
524	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	The only rationale for revisiting IRIS findings is where significant new data have become available since the final IRIS assessment that could inform the weight of the evidence on particular end-points. If that is the case, then the IRIS program should be tasked with updating its previous assessment, using a systematic review protocol that is consistent with the state of the science such as the National Toxicology Program (NTP) method. In its response to comments on the scoping documents, EPA seems to adopt this limited approach to reopening IRIS conclusions, stating that: "OPPT has used IRIS documents as a starting point for identifying key and supporting toxicity studies and initial hazard identification. However, EPA also expects to consider other available hazard and exposure data to ensure that all reasonably available information is taken into consideration. Specifically, EPA will screen information developed after the completion of any IRIS assessment and evaluate the relevant information using OPPT's structured process . . . "	Y	N	N	N	N	N	N	N	N	N	N
525	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy, Systematic Review	N/A	In the problem formulations themselves, however, EPA outlines a much broader approach. It indicates that all studies on IRIS-assessed chemicals will be reviewed using the "study quality" scoring system in EPA's TSCA systematic review document and other as-yet unidentified protocols for reviewing study relevance and weight.61 This process would necessarily involve revisiting the interpretation of studies already evaluated in IRIS, potentially making different judgments about their quality and relevance and modifying overall IRIS determinations of the "best available science" and "weight of the evidence." Moreover, these judgments would be driven by a deeply flawed and unscientific method for reviewing studies that would result in less defensible conclusions than peer reviewed IRIS assessments. Footnote: 61 Typical is this description of EPA's approach in the problem formulation for asbestos, the subject of a comprehensive IRIS assessment: EPA expects to consider and analyze human health hazards as follows: 1) Included human health studies will be reviewed using the evaluation strategies laid out in the Application of Systematic Review in TSCA Risk Evaluations (U.S. EPA, 2018). • Studies will be evaluated using specific data evaluation criteria. • Study results will be extracted and presented in evidence tables by cancer endpoint. 2) Evaluate the weight of the scientific evidence of human health hazard data. • EPA will rely on the weight of the scientific evidence when evaluating and integrating human health hazard data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence. • Assess dose-response information to refine quantitative unit risk for lung cancer and mesothelioma. Review the appropriate human data identified to update, or reaffirm, the 1988 quantitative estimate of the unit risk of asbestos-related lung cancer and mesothelioma by the inhalation route. 3) In evaluating reasonably available data, EPA will determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.	Y	N	N	N	N	N	N	N	N	N	Y
526	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	While TSCA section 26(h) establishes "scientific standards" for science-based decisions under section 6 and other provisions, these standards are general and flexible and do not materially change longstanding criteria used by agencies and the scientific community to assess the reliability, relevance and completeness of scientific evidence. The TSCA standards are consistent with the data review methodologies used by IRIS, other EPA programs and expert organizations like NTP and provide no justification for questioning science judgments and study interpretations made in the IRIS process.	Y	N	N	N	N	N	N	N	N	N	N
527	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	The drawbacks of reopening IRIS assessments are particularly troubling in the case of asbestos. The problem formulation indicates that EPA will review the asbestos database "with the goal of updating, or reaffirming, the unit risk." 63 It describes this review as follows: "Asbestos has an existing EPA IRIS Assessment and an ATSDR Toxicological Profile; hence, many of the hazards of asbestos have been previously compiled and reviewed. EPA relied heavily on these comprehensive reviews in preparing the scope and problem formulation documents. EPA expects to use these documents as a starting point for identifying key and supporting studies to inform the human health hazard assessment, including dose-response analysis. EPA also expects to consider other studies that have been published since these reviews, as identified in the literature search conducted by the Agency for asbestos (Asbestos (CASRN 1332-21-4) Bibliography: Supplemental File for the TSCA Scope Document, EPA-HQ-OPPT-2016-0736). . . . The relevant studies will be evaluated using the data quality criteria in the Application of Systemic Review in TSCA Risk Evaluations document (U.S. EPA, 2018)."	N	N	N	N	N	N	N	N	N	N	Y

528	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	There is no benefit – and considerable downside – in reconsidering the unit risk estimates provided by the IRIS program for asbestos of all fiber types (IRIS 1988) and Libby amphibole asbestos (IRIS 2014). The highly flawed TSCA systematic review method for determining study "quality" would make it difficult for EPA to include important human health and toxicology studies in its chemical hazard assessments if there is any information that is missing or not publicly available. Rejecting or downgrading epidemiological studies on asbestos on this ground could lead EPA to develop a new risk estimate that adopts the asbestos-industry position that chrysotile is safe – a position that was proposed by EPA under the George W. Bush Administration, but rejected by the Scientific Advisory Board, which specifically warned that failure to consider epidemiology and toxicology data for asbestos is problematic.68 These errors and scientific omissions could be repeated if application of the TSCA systematic review criteria results in discarding much of the asbestos epidemiology evidence.69 This would be a huge step back from the settled scientific consensus on the severe dangers of asbestos to public health. Footnotes: 68 SAB consultation on EPA's Proposed Approach for Estimation of Bin-Specific Cancer Potency Factors for Inhalation Exposure to Asbestos. Nov, 2008. EPA-SAB-09-004. https://yosemite.epa.gov/sab/sabproduct.nsf/77CFF6439C00ABF8525750100778O1F/$File/EPA-SAB-09-004-unsigned.pdf 69 See for example Table H-8 of the draft systematic review guidance which lists several pages of "serious flaws that would make epidemiological studies unacceptable for use," including failure to report various sorts of information, which is not considered a measure of study quality by any other peer reviewed systematic review framework.	N	N	N	N	N	N	N	N	N	N	Y
529	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	Even without IRIS assessments, the risks of many substances have been thoroughly reviewed and determined by the Agency and other authoritative bodies but these earlier findings will now be subject to revision as EPA reinterprets studies using its TSCA systematic review document. For example, 1-Bromopropane is classified by the National Toxicology Program as "reasonably anticipated" to cause cancer in humans. In 2016 the EPA Draft Risk Assessment recognized the relevance and reliability of this health endpoint when it derived an inhalation unit risk estimate based on lung tumors. So, it is particularly disturbing that the problem formulation for this chemical states that the "the weight-ofevidence analysis for the cancer endpoint is inconclusive" and it will be evaluated using the flawed TSCA systematic review (EPA 2018 Problem Formulation, p. 45). The concern raised by SCHF, NRDC, and others regarding the industry bias of the TSCA systematic review document makes it likely that a reanalysis will result in a false negative – that is, discounting evidence of cancer (see comments on TSCA systematic review by SCHF, NRDC, Docket EPA-HQ-OPPT-2018-0210 incorporated by reference).	Y	Y	N	N	N	N	N	N	N	N	N
530	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	In sum, we strongly oppose any reopening of IRIS or other findings that have been finalized and represent authoritative determinations by the Agency. As it proceeds with the risk evaluations, EPA should rely on previous IRIS assessments except where significant new data are available. In this case, the IRIS program should evaluate whether the new data warrants modification of its previous determinations of the weight of the evidence for specific endpoints.	Y	N	N	N	N	N	N	N	N	N	N
531	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	XI. EPA Risk Evaluations Should Not Reassess Uses of TCE, MC And NMP That Were Fully Assessed In Its Proposed Section 6(a) Rules for These Chemicals EPA has proposed to ban certain uses of TCE, MC and NMP under section 6(a) of amended TSCA. As the basis for these proposed rules, EPA conducted comprehensive exposure and risk assessments on the targeted uses of the three chemicals and concluded that these uses presented unreasonable risks of injury under TSCA. The EPA assessments were subject to public comment and peer review both during their development and again as part of the rulemaking process. Although the EPA Administrator recently agreed to finalize the proposed MC ban, the problem formulations indicate that EPA will not rely on the completed assessments but will "reassess" the targeted uses for TCE and NMP. We strongly disagree with this approach.	N	N	N	N	N	N	N	Y	Y	Y	N
532	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy, Human Health	N/A	In its peer reviewed IRIS assessment for TCE, EPA concluded that "[i]ncreased incidence of fetal cardiac malformations was identified as the most sensitive health endpoint within the developmental toxicity domain." This finding was reaffirmed in EPA 2014 TCE Work Plan Chemical Assessment. In 2016, EPA scientists published a systematic review of the data confirming the basis for linking TCE exposure to congenital heart malformations. Congenital heart effects can be disabling or even deadly. The significant and unreasonable risks posed by TCE in consumer and industrial products, particularly from exposures during pregnancy, led EPA to propose to ban its use in aerosol and vapor degreasing operations.	N	N	N	N	N	N	N	N	N	Y	N
533	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy, Human Health	2.4.2	Despite EPA's repeated findings of heart malformations linked to TCE, the problem formulation states that: "The relevant studies will be evaluated using the data quality criteria in the Application of Systematic Review in TSCA Risk Evaluations document." This evaluation could result in EPA rejecting the peer-reviewed findings of earlier assessments. Significantly, at the same time as TSCA issued its systematic review guidance for public comment, an industry-sponsored consulting firm published its analysis of why the studies linking TCE with heart defects were "not sufficiently reliable for the development of toxicity reference values." Since the industry-sponsored publication uses reasoning similar to that in the flawed TSCA systematic review guidance, it seems likely that the TSCA risk evaluation may similarly dismiss the evidence of congenital heart defects. Disregarding this important scientific evidence of harm would put the public at great risk.	N	N	N	N	N	N	N	N	N	Y	N
534	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A	It would be both scientifically indefensible and counterproductive for the Agency to reopen these assessments for yet another round of public input and to redo the extensive analyses they contain simply so industry commenters can have another bite at the apple on findings they dislike. The next step in the rulemakings should be to issue final rules as quickly as possible. These rules, once issued, should close the book on the targeted uses and enable EPA to focus its risk evaluations on uses that have not yet been assessed.	Y	N	N	N	N	N	N	N	N	N	N
535	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure	2.2, 2.3	XII. EPA Should Not Presume That Occupational Exposure Standards Are Fully Protective of Workers, Can be Equated with the Absence of Unreasonable Risk and are Representative of Actual Worker Exposure Occupational exposure is significant for nearly all of the 10 chemicals and should be a major focus of EPA's risk evaluations. The problem formulations indicate that when evaluating occupational risks, the Agency will heavily weigh mandatory and voluntary workplace standards and "will consider the influence of the recommended exposure limits on occupational exposures." We agree that existing workplace standards are relevant in determining risks to workers. However, for several reasons, it would be unjustified for EPA to presume that these standards are fully protective of workers or that their existence can be equated with the absence of unreasonable risk.	Y	N	N	N	N	N	N	N	N	N	N

536	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Exposure	2.3	First, TSCA and the Occupational Safety and Health Act (OSH Act) apply differing standards of protection and the level of risk reduction afforded by OSHA limits may well be inadequate to satisfy the more stringent requirements of TSCA. OSHA is only authorized to adopt workplace standards for chemicals presenting "significant risks of harm," a term interpreted by the Supreme Court's Benzene decision as requiring OSHA to demonstrate by substantial evidence that "it is at least more likely than not that longterm exposure to [a chemical] presents a significant risk of material health impairment." By contrast, the term "unreasonable risk" under TSCA does not impose this high threshold for regulation. Further, OSHA may impose only economically and technologically feasible limits on exposure. However, economic and technological considerations have no bearing on EPA's determinations of unreasonable risk, which cannot take into account cost and other non-risk factors under section 6(b)(4)(A).80 Finally, while OSHA is only authorized to place limits on exposure, TSCA provides a broad array of remedies, including bans of production and use, which may provide a level of protection that OSHA lacks authority to impose. Footnote: 80 Based on these considerations, EPA decided against referring to OSHA workplace risks from exposure to trichloroethylene (TCE) under section 9(a) of TSCA, even though OSHA had earlier promulgated a workplace standard for TCE. In deciding to address risks to workers through a section 6(a) rulemaking instead, EPA compared its authority under TSCA to eliminate these risks to that of OSHA, concluding that "there is no other federal law that provides authority to prevent or sufficiently reduce these . . . exposures." It further concluded that risks that EPA found to be "unreasonable" under TSCA might not be deemed "significant" by OSHA. 82 Federal Register 7432, 7454 (January 19, 2017).	Y	N	N	N	N	N	N	N	N	Y	N
537	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Exposure	2.3	Second, a number of the OSHA standards that apply to chemicals subject to the first 10 risk evaluations were developed many years ago and do not reflect current data and scientific understanding of the health effects of the regulated chemicals.81 Thus, the levels of exposure allowed by these standards may be unsafe when evaluated using the best available science. Footnote: 81 OSHA has two types of standards. Under section 6(a) of the OSH Act, OSHA adopted hundreds of PELs in 1971 that were, at that time, considered national consensus standards. They have not been updated since and are based on science from the 1960s or earlier. Since 1971, OSHA has regulated only about 40 chemicals under section 6(b). These more comprehensive standards are based on thorough evaluation of health effects and a determination that risks are significant. OSHA has 6(b) standards regulating only asbestos and MC. It has PELs (adopted under 6(a)) for PERC and TCE but not for the other 10 chemicals. In the case of both asbestos and MC, OSHA's published Federal Register preambles found that even at the revised PEL, employees continued to be exposed to significant risks i.e., risks above 1/1000 – OSHA's definition of significant risk.	Y	N	N	Y	N	N	N	Y	N	Y	Y
538	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Exposure	2.2, 2.3	Third, OSHA does not cover all workers. It only covers private sector employees of employers. It does not cover employees of federal, state or local governments. These workers might include building maintenance people exposed to asbestos, hospital workers exposed to PERC when laundering linens or other supplies, etc. OSHA also does not cover independent contractors. In the construction sector, many people performing remodeling work, such as stripping paint and otherwise using MC, or removing asbestos insulation are independent. These workers have no OSHA protection. So even if OSHA standards were adequately protective of the workers they covered, there would still be a need for EPA to act under TSCA to make sure all workers had an equivalent level of protection.	Y	N	N	N	N	N	N	Y	N	N	Y
539	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Exposure	2.2, 2.3	Fourth, there is no basis for EPA to assume across-the-board compliance with OSHA standards. As the Agency pointed out in its proposed section 6(a) rule for MC paint removal products, exposures above the OSHA limit have been well documented.82 To determine actual workplace exposures, we encourage EPA to obtain and review all the data gathered by law under OSHA's Access standard, 29 CFR 1910.1020 which "provide[s] employees and their designated representatives a right of access to relevant exposure and medical records; and to provide representatives of the Assistant Secretary a right of access to these records in order to fulfill responsibilities under the Occupational Safety and Health Act."83 (1910.1020(a)). This would provide a basis for comparing actual exposures to OSHA standards and, for specific chemicals, determine whether and to what extent OSHA standards reliably limit exposure. While these data will provide a valuable snapshot of exposures, it should be kept in mind that OSHA exposure monitoring data is not systematic or comprehensive, and therefore may not be representative of workplace chronic or peak exposures that are likely to be missed with snapshot monitoring. Footnotes: 82 Studies referenced by EPA found widespread non-compliance with the OSHA MC workplace standard during paint and coating removal, resulting in MC exposures above the OSHA standard, despite the mandatory nature of the OSHA requirements. 82 FR 7405 (Ref. 70) 83 These data include: • "Environmental (workplace) monitoring or measuring of a toxic substance or harmful physical agent, including personal, area, grab, wipe, or other form of sampling, as well as related collection and analytical methodologies, calculations, and other background data relevant to interpretation of the results obtained" (1910.1020(c)(5)(i)); and, • "Biological monitoring results which directly assess the absorption of a toxic substance or harmful physical agent by body systems (e.g., the level of a chemical in the blood, urine, breath, hair, fingernails, etc.)" (excluding drug and alcohol testing) 1910.1020(c)(5)(ii). For example, the OSHA standard for methylene chloride can be found at 29 CFR 1910.1052, which describes details of mandatory exposure monitoring, employee notification requirements, and long-term retention of the monitoring results. Under OSHA's Access standard, 29 CFR 1910.1020 (D)(7)(ii), employers must retain these records for 30 years.	Y	N	N	N	N	N	N	Y	N	N	N
540	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure	2.2, 2.3	Finally, as EPA has recognized, some of the industrial hygiene strategies embodied in OSHA standards – such as labels and respirators – are known to be of limited effectiveness in protecting workers and have been required by OSHA to compensate for the lack of effective engineering controls or constraints on its authority, not because they are uniformly protective. For example, in its proposed section 6(a) rules for TCE, MC and NMP, EPA analyzed a universe of 48 studies [84] and concluded that: • [C]onsumers and professionals do not consistently pay attention to labels; consumers and professional users often do not understand label information; consumers and professional users often base a decision to follow label information on previous experience and perceptions of risk; even if consumers and professional users have noticed, read, understood, and believed the information on a hazardous chemical product label, they may not be motivated to follow the label information, instructions, or warnings; and consumers and professional users have varying behavioral responses to warning labels, as shown by mixed results in studies. Footnote: 84 OPPT summarized these studies in a paper entitled: The Effectiveness of Labeling on Hazardous Chemicals and Other Products (March 2016) (Ref. 33 in rulemaking docket).	Y	N	N	N	N	N	N	Y	Y	Y	N

541	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure	2.2, 2.3	Similarly, EPA cautioned that "there are many documented limitations to successful implementation of respirators," explaining that: "Not all workers can wear respirators. Individuals with impaired lung function, due to asthma, emphysema, or chronic obstructive pulmonary disease for example, may be physically unable to wear a respirator. Determination of adequate fit and annual fit testing is required for a tight fitting full-face piece respirator to provide the required protection. Also, difficulties associated with selection, fit, and use often render them ineffective in actual application, preventing the assurance of consistent and reliable protection, regardless of the assigned capabilities of the respirator. Individuals who cannot get a good face piece fit, including those individuals whose beards or sideburns interfere with the face piece seal, would be unable to wear tight fitting respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue and reduced work efficiency (63 FR 1156, January 8, 1998). According to OSHA, 'improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health. (63 FR 1189-1190)."	Y	N	N	N	N	N	N	Y	Y	Y	N
542	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Exposure	2.2, 2.3	Because of these considerations, EPA cannot assume that, simply because they are required by OSHA standards, labeling or respirators will in fact provide adequate worker protection and successfully prevent unsafe exposure. Rather, as it did in its proposed rules for MC, TCE and NMP, EPA should explicitly recognize the limitations of these industrial hygiene controls and determine whether risks to workers are unreasonable given that labeling and respirators are often unprotective and unreliable in the real world.	Y	N	N	N	N	N	N	Y	Y	Y	N
543	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General	2.2, 2.3	Conclusion The EPA problem formulations are replete with questionable exclusions and loopholes, failures to require necessary testing, deviations from accepted scientific methods and refusal to accept previous peer reviewed determinations of risk. As a result, the Agency is on a path to produce evaluations that ignore important exposure pathways and at-risk populations, disregard evidence of adverse effects and reach misleading, incomplete and understated conclusions about risk that weaken public health protection. EPA should put the 10 evaluations on hold, rethink how they are being conducted, and reinitiate them in accordance with the law and principles of sound science.	Y	N	N	N	N	N	N	N	N	N	N
544	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General	N/A	The Chemical Products and Technology Division of the American Chemistry Council (ACC-CPTD)1 submits the enclosed comments on the problem formulation of the trichloroethylene (TCE) risk evaluation under the Toxic Substances Control Act (TSCA), as amended by the Lautenberg Chemical Safety Act (LCSA) enacted in June 2016. Footnote: 1 ACC represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. ACC's Chemical Products and Technology Division is composed of a wide range of more than 60 self-funded product and sector groups that are focused on specific chemistries and related technologies. Members participating in these groups include large and small manufacturers, formulators, downstream users, distributors, suppliers and other trade associations.	N	N	N	N	N	N	N	N	N	Y	N
545	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, Exposure, Human Health	2.4, 2.5	ACC-CPTD supports the approach to risk evaluation outlined in the draft problem formulation for TCE, particularly in relation to the following – • EPA has appropriately defined the conditions of use for the risk evaluation to include those uses addressed in the 2014 assessment and to exclude potential exposure pathways for which long-standing regulatory and analytical processes already exist under other statutes administered by the Agency (Section 2.5); and • Previous Agency assessments of TCE have not incorporated a systematic review approach to evaluate studies; a reevaluation of the key studies identified by these previous assessments, more recent information relating to health endpoints reported by these studies, and available mechanistic data is critical to a robust analysis of human health hazards associated with TCE. This is particularly important in relation to the assessment of fetal cardiac malformations.	N	N	N	N	N	N	N	N	N	Y	N
546	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, Exposure	N/A	1.0 Introduction The Chemical Products and Technology Division of the American Chemistry Council (ACC/CPTD) appreciates the opportunity to submit comments on the Office of Pollution Prevention and Toxics (OPPT) Problem Formulation of the Risk Evaluation for Trichloroethylene (TCE) (the Problem Formulation) under the amended Toxic Substances Control Act (TSCA). As described in the Problem Formulation, the purpose of the document is to outline the approach for analyzing and characterizing the potential risk from exposure to TCE uses. ACC/CPTD appreciates the focus that the Environmental Protection Agency (EPA) has brought to this process in such a limited time period. In particular, and as described below, ACC/CPTD supports EPA's approach to include all current conditions of use in the risk evaluation, while excluding historic ("legacy") uses and applications with existing regulatory frameworks under other EPA statutes. This will allow OPPT to focus its assessment of risks associated with exposure to TCE in an efficient and effective manner. It will further allow OPPT to avoid the potential for conflict with EPA's long standing approaches to addressing TCE under its other statutory authorities. It is critical that the Problem Formulation follow a clear and transparent approach to identifying and assessing the available hazard and exposure data, such as that outlined in the OPPT Systematic Review Principles. This is necessary to ensure transparency and compliance with the requirements of TSCA Section 26.	N	N	N	N	N	N	N	N	N	Y	N
547	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, Policy, Human Health	2.4.2	As noted in the Problem Formulation, existing health assessments of TCE conducted by EPA – including the 2011 Integrated Risk Information System (IRIS) assessment conducted by the National Center for Environmental Assessment (NCEA) and OPPT's own 2014 assessment under the Work Plan Chemicals program – do not comply with the requirements for the use of the best available science and weight of scientific evidence (WOE) under TSCA §26 and as defined in OPPT's risk evaluation procedures. In particular, the previous EPA assessments fail to adequately apply the weight of evidence when evaluating non-cancer health endpoints associated with TCE exposure, including fetal cardiac malformations (FCM). In evaluating the potential developmental toxicity of TCE under TSCA, OPPT is required to conduct an independent, systematic review of the available information for TCE, including FCM, as outlined in the risk evaluation rule. Prior assessments for TCE that evaluated FCM should not be relied on as part of this risk evaluation process. As the Problem Formulation suggests, significant new information on cardiac defects has become available since the IRIS and Work Plan reviews and ACC/CPTD anticipates that further information will be available in time for the OPPT risk evaluation.6 Footnote: 6 The Halogenated Solvents Industry Alliance (HSIA) has initiated a drinking water study of the effects of TCE on fetal heart development in rats that is expected to be completed in time for inclusion in the OPPT risk evaluation.	N	N	N	N	N	N	N	N	N	Y	N

548	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, Policy	2.2	2.0 OPPT has Appropriately Defined the Conditions of Use for Risk Evaluation ACC/CPTD supports EPA's approach to include current conditions of use in the risk evaluation, while excluding historic ("legacy") uses and applications with existing regulatory frameworks under other EPA statutes. We support OPPT's decision to include the degreasing and spot cleaning uses of TCE in the current risk evaluation and to exclude consideration of potential exposures that are addressed under other statutes administered by EPA. As noted, OPPT conducted assessments of TCE use in degreasing and spot cleaning in 2014 as part of its Work Plan assessment program. These assessments, however, were not conducted according to the scientific standards specified in Section 26 of TSCA, as amended by the Lautenberg Chemical Safety Act (LCSA) passed in June 2016, and should not form the basis for the current evaluation. While the amended TSCA provides for finalization of rulemakings based on assessments completed prior to passage of the amendments, finalizing rules based on the 2014 assessments could prejudice any subsequent assessment of TCE or create inconsistency in OPPT's approach to considering the chemical. We acknowledge that OPPT may decide to proceed with rulemakings for degreasing and spot cleaning, but such rulemakings should be based on an updated risk evaluation conducted in compliance with TSCA Section 26.	N	N	N	N	N	N	N	N	N	Y	N
549	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, RegNex	2.3	OPPT's decision to exclude potential exposures addressed under other statutes administered by EPA represents an inherently practical conclusion and one that is wholly consistent with the statute. From a practical standpoint, requiring OPPT to repeat evaluations of exposure pathways conducted under other EPA-administered statutes as part of a TSCA risk evaluation would be time-consuming and non-productive and likely cause OPPT to miss the 3-year deadline provided by the statute for completion of the evaluation. As for statutory compliance, Section 9 of TSCA instructs the Administrator to coordinate actions under the Act with those taken under other Federal laws administered by the Agency. It further provides EPA with the discretion to use these other laws – in lieu of TCSA - to address risks to health or the environment. In the Problem Formulation, OPPT indicates that it worked closely with EPA offices responsible for assessing and managing exposures under other statutes administered by EPA. As a result of this interaction, OPPT concluded that the Agency has ongoing programs to address TCE exposures from ambient air, ambient water, drinking water, disposal, sediment, and soil under the Clean Air Act, Clean Water Act, Safe Drinking Water Act, and Resource Conservation and Recovery Act, respectively. Consistent with the authority granted under Section 9, ACC supports the exclusion of these potential exposure pathways from the risk evaluation under TSCA.	N	N	N	N	N	N	N	N	N	Y	N
550	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, Policy	2.2	EPA also has indicated its decision to exclude "legacy" uses and disposal 9 from risk evaluations under TSCA on the basis that Section 6 focuses on "prospective, ongoing uses" of the substance. The EPA rulemaking further notes that TSCA does not provide the OPPT with an effective tool to address risks found to arise from uses (and exposures) for which there is no ongoing commercial manufacture, processing, or distributing. EPA correctly concludes, moreover, that "absent clear intent from Congress, courts will not hold a statute to be retroactive, or uphold an agency regulation that seeks to have such an effect." In light of the fact that potential exposures from legacy disposal of TCE are actively being addressed under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), ACC/CPTD agrees that there is no need to consider such exposures as part of the risk evaluation. Footnote: 9 In the risk evaluation rulemaking, EPA defines legacy disposal as disposals that have already occurred (e.g., a chemical substance currently in a landfill or in groundwater.) 82 Fed. Reg. at 33729.	N	N	N	N	N	N	N	N	N	Y	N
551	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Exposure	2.3, 2.6	3.0 OPPT Should Clarify How It Will Consider Worker Exposures as Part of the Risk Evaluation In the Problem Formulation OPPT has identified occupational exposures to TCE, but has not explained how it plans to assess exposures to workers or what risk management approaches might arise from the evaluation. ACC has submitted more detailed comments on the exposure assessments to be conducted as part of the risk evaluations, but ACC/CPTD wishes to emphasize some specific points relative to evaluating occupational risks. We are concerned about the suggestion on page 58 that OPPT use release data from the Toxic Release Inventory (TRI) or National Emissions Inventory (NEI) to estimate occupational exposure. Although TRI and NEI data are useful for assessing potential ambient air exposures to a substance, they can provide no insight into exposures in the workplace. To the extent that exposure data is lacking for a particular condition of use, EPA should engage the affected industries to provide such data and only consider TRI and NEI data as a last resort.	N	N	N	N	N	N	N	N	N	Y	N
552	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, Policy	N/A	Section 9 of TSCA outlines a process for coordinating with the Occupational Safety and Health Administration (OSHA) and other federal agencies in the implementation of any risk management activities arising from the risk evaluation. The Problem Formulation describes OPPT's interactions with other EPA offices, but is silent on any discussions it has had with OSHA. In light of the significant differences in the criteria used by the two agencies in assessing potential risks, it is critically important that stakeholders understand how OPPT plans to coordinate its authority with that of OSHA.	N	N	N	N	N	N	N	N	N	Y	N
553	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General	N/A	4.0 Existing Assessments of TCE Are Not Consistent with OPPT's Systematic Review Principles or Section 26 of TSCA With respect to TCE, we are further encouraged that the Problem Formulation describes how aspects of the systematic review guidance will be applied. In particular, relevant studies will be evaluated using the data quality criteria for endpoints of interest, including immunotoxicity and reproductive and developmental toxicity. As discussed earlier, the TCE reviews conducted for IRIS in 2011 and for the Work Plan in 2014 did not include a systematic review approach (i.e., an approach that included critical appraisal of individual studies) to evaluating the available data for FCM effects and cannot be considered to be WOE reviews as defined by the risk evaluation rule and as required by Section 26 of TSCA.	N	N	N	N	N	N	N	N	N	Y	N
554	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, Human Health	N/A	5.0 Systematic Review of the Key Study Suggesting Cardiac Effects Likely Will Disqualify It from Further Consideration Given that the Problem Formulation references the previous IRIS and OPPT assessments that identify FCMs as the most sensitive health endpoint, it is important to acknowledge and address the controversy surrounding the cardiac data. The systematic review process described by OPPT, and in particular the process for evaluation of data quality for key studies via the criteria in the Application of Systematic Review in TSCA Risk Evaluations, should provide a platform for objectively evaluating the reliability of the FCM data – as well as other data that EPA will assess, including immune and cancer endpoints.	N	N	N	N	N	N	N	N	N	Y	N

555	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health	2.4.2	The Problem Formulation further indicates a heavy reliance on previously compiled and systematically reviewed data for characterization of human health endpoints. As discussed above, the human health data for TCE have not been subject to systematic review by EPA. Systematic review implies a specific process – it is not synonymous with reviewing information systematically or simply conducting a systematic literature search. Thus, in conducting the TSCA risk evaluation, it is important to recognize that while a 2016 update of available human, animal, and mechanistic data by EPA staff represents a good compilation of the available cardiac data, it falls well short of the systematic review approach described in the OPPT guidelines. Of particular concern is the failure of the 2016 analysis by Makris et al. to conduct a critical appraisal of validity of individual studies. Under OPPT guidelines, the evaluation of study quality directs that those with well documented flaws are eliminated from further consideration. Regarding the key study reporting FHM in laboratory animals by Johnson et al. (2016), Makris et al. identify several serious flaws that would disqualify the study from further consideration under the OPPT guidelines, including – • Test Design: Not all control groups were run concurrently with the exposure groups; control data from metabolite studies conducted from 1992-1994 were combined with study data from 1994-95 and gestation-only data from 1989-1993; • Exposure Characterization: Information on the preparation of the test substance was not reported; as indicated by the information submitted to this docket by the Halogenated Solvents Industry Alliance (HSIA), significant loss of TCE from drinking water samples can occur during sample preparation unless steps are taken to ensure the integrity of the samples; • Exposure Characterization: The reported exposure data could not be validated for some of the exposure groups; the earlier studies included in the Johnson et al. analysis used tap water of unknown composition in preparing samples for the studies conducted in the early 1990s; and • Data Presentation & Analysis: The statistical methods used were not appropriate; the authors calculated per-litter statistics by adding the total number of litters with at least one cardiac defect by the total number of litters rather than examining the proportion of pups per litter as recommended by EPA.	N	N	N	N	N	N	N	N	N	Y	N
556	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health	2.4.2	Despite these serious design and reporting limitations, and the inability of other laboratories to duplicate the results, Makris et al. conclude that "on the whole" Johnson et al. is considered suitable for use deriving toxicity values. However, the Makris et al. reassessment of the TCE-FCM database lacks key elements required for a transparent systematic review, including protocol development and a failure to include a risk-of-bias assessment.	N	N	N	N	N	N	N	N	N	Y	N
557	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health	2.4.2	In addition to the issues identified by Makris et al., study design shortcomings that would otherwise lead to rating the Johnson et al. study as low quality include – • Non-concurrent dose groups: The comparison of data sets from TCE exposure groups that were not tested concurrently (i.e., high-dose groups reported in an earlier study with low-dose groups later reported in Johnson et al.); • Ad hoc pooling of control data: Data from unexposed "control groups" that were used in different experiments at different times across a 6-year period were pooled and used as the basis of comparison with TCE exposure groups; and • Unconventional dose spacing: The difference between the highest and lowest in TCE dose groups was nearly six orders of magnitude.	N	N	N	N	N	N	N	N	N	Y	N
558	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health	2.4.2	More recently, Wikoff et al. (2018) conducted a risk-of-bias analysis of the heart defects data for TCE that more closely aligns with many of the elements of the OPPT systematic review guidance. Such an evaluation of the risk of bias is a critical element of any systematic review. Using the National Toxicology Program's tool, the authors conclude that the study by Johnson et al. had the highest risk of bias of all of the animal studies in the evidence base. As a result of the high risk of bias, inconsistent findings with all other animal studies with lower bias ratings, and the inability to replicate study findings, the authors conclude that "the Johnson et al. study is not sufficiently reliable for hazard characterization or development of noncancer toxicity values."	N	N	N	N	N	N	N	N	N	Y	N
559	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health	2.4.2	In evaluating the human studies, moreover, Wikoff et al. conclude that "there are no data of sufficient quality" to develop conclusions regarding the potential for health effects. This conclusion is consistent with that reached by Bukowski (2014) as well as Makris et al. Of the nine human studies included in all three reviews, only three provide evidence for an association with FCM. All three of these studies lack accurate exposure information and fail to adequately control for potential confounding factors. Among the negative studies, are investigations of large, high-profile populations in Woburn, MA and Camp Lejeune, NC over extended periods of time (greater than 20 years), as well as a study in New Jersey that included the largest birth population of any of the studies assessed.	N	N	N	N	N	N	N	N	N	Y	N
560	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health	2.4.2	Based on the risk of bias and data integration findings from animal and human studies, Wikoff et al. concluded that FCM are not a suitable end point upon which to base a quantitative assessment. This is in agreement with conclusions reached in an earlier European occupational exposure assessment of the TCE-FCM database – • Epidemiological evidence does not support the occurrence of this teratogenic effect after human uptake of TCE from contaminated drinking water, and animal studies demonstrate such effects at much higher doses than those relevant for [occupational exposure level] derivation . . . In addition, positive results are contradicted by qualified negative studies . . . An overall evidence for development of congenital heart disease due to TCE exposure in relevant doses is not sufficiently supported.	N	N	N	N	N	N	N	N	N	Y	N
561	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health, Eco Health	2.4	In addition to the animal and human studies, Makris et al. pointed to a number of in vitro and in ovo (avian) studies to support their conclusion that the Johnson et al. study is adequate for quantitatively assessing TCE risk. As with the other data, the EPA scientists did not subject the mechanistic data to a systematic review. Importantly, there are notable shortcomings in both the design and relevance of these studies. These limitations include – • the use of TCE exposure levels in in vitro studies that are orders of magnitude higher than exposures reported in the animal and human studies; and • critical differences in the avian vs. mammalian models, including differences in exposure duration, the irrelevant exposure route, and the lack of both maternal influence and placenta.	N	N	N	N	N	N	N	N	N	Y	N
562	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health, Eco Health	2.4	The relevance of the reported in vitro and avian studies to human health is highly questionable. The uncertainties of extrapolating dose levels from in ovo study results to mammals and humans are considerable, making these studies not directly applicable to human health risk assessment. In addition, in discussing a potential mechanism of action for cardiac effects, Makris et al. link the findings from 32 studies without assessing whether the studies are equally relevant and the results valid in constructing the proposed mechanism.	N	N	N	N	N	N	N	N	N	Y	N
563	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health, Eco Health	2.4	A more recent study published by Harris et al. (2018) reported on the in vitro and in ovo effects of TCE on the expression of the transcription factor HNF4a (Hepatocyte Nuclear Factor 4 alpha). Harris et al. suggest that HNF4a is a key protein involved in cardiac development. However, the study design is limited and inadequate for extrapolating the findings to humans and the results are poorly reported (e.g., errors in labeling, inadequate information regarding the statistical significance of the findings). The functional endpoint examined in this study (i.e., cardiac contraction) in particular is especially unpersuasive as the controls demonstrated considerable method variability.	N	N	N	N	N	N	N	N	N	Y	N
564	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health	2.4	Makris et al. suggest that the mechanistic data is sufficient for developing a "preliminary conceptual model of an adverse outcome pathway (AOP) for valvulo-septal defects resulting from TCE exposures." This is a key assertion used by these authors to support their argument that the mechanistic data "supports the biological plausibility of an effect on cardiac development with exposure to TCE." However, an AOP describing the complete process from initial biomolecular perturbations to the various and diverse types of cardiac malformations that were reported in the TCE-exposed rats in the Johnson et al. study has not been proposed to date. This highlights the important data gaps in the current knowledge base, further calling into question the plausibility of the TCE-FCM hypothesis.	N	N	N	N	N	N	N	N	N	Y	N

565	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, Human Health	N/A	With this in mind, EPA/OPPT should evaluate the TCE-FCM mechanistic literature in a systematic fashion, including via the application of clear and objective study quality metrics that will allow for a comprehensive assessment of the quality of this database.	N	N	N	N	N	N	N	N	N	Y	N
566	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, Human Health	2.4	Taken together, the available lines of evidence (i.e., animal, human, and mechanistic) do not support the use of the Johnson et al. study to develop toxicity values for TCE. OPPT should eliminate the use of the Johnson et al. study in its risk assessment as it does not meet the minimum necessary quality standards.	N	N	N	N	N	N	N	N	N	Y	N
567	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, Human Health, Eco Health	2.4	6.0 Elimination of the Johnson et al. Study is Supported by the Lack of Evidence in Other Laboratory Analyses TCE has only been associated with cardiac defects in animal studies conducted at the University of Arizona laboratory. The first report from the Arizona lab was based on the injection of very high concentrations of TCE directly into the fertilized chick eggs which are of questionable relevance to humans. Subsequent studies from the laboratory in which TCE was administered to rats in drinking water produced anomalous dose-response results achieved through non-conventional statistical analysis. Johnson et al. reported that TCE produces cardiac teratogenicity and no other adverse developmental effects. No other laboratory has been able to reproduce these results.	N	N	N	N	N	N	N	N	N	Y	N
568	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health	2.4	In several well-designed and conducted studies using standard techniques for identifying developmental hazards, rats, mice, and rabbits were exposed to TCE by inhalation at doses as high as 600 ppm (Carney et al. 2006) and rats were exposed by oral gavage to 500 mg/kg/day of TCE (Fisher et al. 2001). Neither of these studies reported exposure related developmental toxicity, even in the presence of maternal toxicity. Furthermore, neither reported significant evidence of specific cardiac teratogenicity.	N	N	N	N	N	N	N	N	N	Y	N
569	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health	2.4	Importantly, these two studies used the highest TCE exposure concentrations and are not limited by the study design and reporting flaws that underlie the Johnson et al. study. Further, the Fisher et al. developmental toxicity study was explicitly designed to replicate the high-dose TCE-FCM reported in Johnson et al. The investigators even enlisted the help of Dr. Paula Johnson, the lead scientist of the Johnson et al. study, for her expertise on the fetal heart dissection and evaluation technique used by the University of Arizona laboratory. Despite these efforts, Fisher et al. were unable to reproduce the FCM reported in the Johnson et al. study.	N	N	N	N	N	N	N	N	N	Y	N
570	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health	2.4	While the Fisher et al. study was conceived as a hazard identification study, and therefore had some study design differences relative to Johnson et al.,40 the authors reported no statistical difference in FCM incidence in the fetuses from vehicle control and TCE-treated dams. The Fisher et al. study was of higher quality in design and reporting relative to Johnson et al., included concurrent controls, included a positive control (retinoic acid) that demonstrated the efficacy of the FCM evaluation technique, and reported appropriate per-litter statistics. Although several possible explanations for the differences in the results reported in the two studies have been suggested, the most likely is the use of non-traditional statistical analysis – first in the use of per-fetus, rather than per-litter, results and subsequently in the use of pooled, non-concurrent control groups as the basis for comparison. Footnote: 40 For example, TCE was administered via daily oral gavage in the study by Fisher et al. instead of via drinking water and the pregnant rats were exposed during the primary period of organogenesis (gestation days 6–15) instead of throughout gestation.	N	N	N	N	N	N	N	N	N	Y	N
571	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health	2.4	A subsequent study by Carney et al. was designed to determine if inhalation exposures would result in FCMs. This was a high-quality experimental animal study designed and performed according to GLP protocols set forth in EPA and Organisation for Economic Co-Operation and Development (OECD) guidelines for developmental toxicity testing (OPPTS 870.3700; OECD Guideline 414). The authors reported no significant increase in FCMs, despite TCE concentrations ranging from 125,000- to 1,500,000-fold higher than the EPA IRIS reference values, which are in part based on route-to-route extrapolation of FCM data from the Johnson et al. study.	N	N	N	N	N	N	N	N	N	Y	N
572	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health	2.4	As a result of the concerns about the data reported by Johnson et al., California's Office of Environmental Health Hazard Assessment (OEHHA) concluded that – "[t]he data for this [Johnson et al.] study were not used to calculate a public-health protective concentration since a meaningful or interpretable dose-response relationship was not observed. These results are also not consistent with earlier developmental and reproductive toxicological studies done outside this lab in mice, rats, and rabbits: The other studies did not find adverse effects on fertility or embryonic development, aside from those associated with maternal toxicity."	N	N	N	N	N	N	N	N	N	Y	N
573	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health	2.4	Similarly, in evaluating the TCE science, the NRC (2006) noted that the "low-dose studies showing a positive correlation in TCE-induced cardiac teratogenesis showed unusually flat dose-response curves and came from a single laboratory. The results need to be replicated in another laboratory to clarify the dose-response relationship. As indicated previously, no lab has been able to replicate the results reported by Johnson et al. As of now, the inhalation study conducted by Carney et al. represents the most recent experimental animal study designed to examine potential TCE-FCM and also reflects the relevant route of exposure for development of inhalation toxicity values.	N	N	N	N	N	N	N	N	N	Y	N
574	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Other	N/A	7.0 OPPT's Literature Search is Lacking Two Key Studies The 2017 Scoping Document and 2018 Problem Formulation for TCE include the literature search and screening strategies developed by OPPT, as well as the initial results of these activities. OPPT notes that the TSCA systematic review strategy the Office plans to use for the risk evaluation of the first ten chemicals will be iteratively developed as it carries out the risk evaluations for these initial chemicals. Thus, OPPT states in the 2017 TCE Bibliography (supplemental file): "Additional on topic references not initially identified in the initial search may also be identified as the systematic review process proceeds." However, the Problem Formulation indicates that key studies will be identified based on secondary sources (e.g., ATSDR Toxicological Profile and previous EPA assessments) along with a literature search as presented in the supplemental file. It is not clear if an additional literature search for TCE will be conducted beyond that already described in the Problem Formulation.	N	N	N	N	N	N	N	N	N	Y	N
575	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health	2.4	The following publications should be included in the risk evaluation for TCE – • Beliles et al. (1980): This is the publicly available technical laboratory report that supplements Hardin et al. (1981). Hardin et al. (1981) is a general summary of a series of teratogenicity studies that includes TCE inhalation experiments in pregnant rats and rabbits. The experiments were conducted by a contract research laboratory (Litton Bionetics) on behalf of the National Institute for Occupational Safety and Health (NIOSH), and the technical details of these experiments are reported in the Beliles et al. (1980) report. • Wikoff et al. (2018): A risk-of-bias evaluation of the animal and human studies used as the basis for the IRIS and Makris et al. assessment of the association between TCE and FCM. The authors used the OHAT 2015 risk-of-bias tool to evaluate data quality of the relevant literature.	N	N	N	N	N	N	N	N	N	Y	N
576	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health	2.4	The former report is important for evaluating the data quality of the Hardin et al. paper, and the latter is the only example in the literature of a systematic evaluation of risk of bias and subsequent integration of TCE-FCM literature using readily accepted systematic review methods. OPPT should include these as "on-topic" references in the "Human Health Hazard Literature" and "OPPT Risk Assessment" categories of the OPPT TCE literature database.	N	N	N	N	N	N	N	N	N	Y	N
577	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, Human Health	N/A	For TCE specifically, Wikoff et al. address the differentiation of internal and external validity as it relates to evaluating and integrating evidence from animal studies and human studies.	N	N	N	N	N	N	N	N	N	Y	N

578	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	General	N/A	Thank you for the opportunity to provide comments on the problem formulation document for trichloroethylene (TCE). Silent Spring is a non-profit research organization that focuses on understanding the toxicity of and exposure to chemicals that may increase the risk of breast cancer. Breast cancer is the most common form of cancer in American women, and a leading cause of death from cancer in women. Our research is focused on identifying environmental risk factors because no one should have an increased risk of breast cancer from exposure to chemicals.	N	N	N	N	N	N	N	N	N	Y	N
579	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Exposure	2.2.2.1	Conditions of Use (Section 2.2.2.1) We applaud the EPA's decision to include conditions of use identified in EPA's 2017 Scope of the Risk Evaluation for Trichloroethylene, including use as an intermediate or reactant, lubricant, or adhesive, and use as an ingredient in consumer products (EPA 2017). We are also encouraged to see the EPA include uses previously assessed in EPA's 2014 risk assessment (solvent degreaser, spotting agent, and protective coating for arts and crafts) (EPA 2014). These inclusions will help EPA come to a more accurate evaluation of any unreasonable risk posed by TCE, especially from cumulative exposures. However, since TSCA section 26(l)(4) explicitly allows rulemaking on the bases of uses included in the 2014 Work Plan assessments and EPA has already begun to issue risk determinations and rules on that basis, EPA should not subject uses and exposures undergoing rulemaking to re-evaluation. Instead, EPA should incorporate its existing data and conclusions and focus on evaluating uses and exposures that have not undergone rulemaking.	N	N	N	N	N	N	N	N	N	Y	N
560	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Exposure	2.2.2.1	The basis for excluding consumer paints and coatings from evaluation is unclear. The EPA is excluding evaluation of TCE in paints and coatings for consumer use based on EPA's 2016 significant new use rule (SNUR), which reports that TCE is not expected to be present in consumer products other than cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, and pepper spray (EPA 2016). However, the 2016 SNUR relies on analyses performed for the 2014 TCE Work Plan Chemical Risk Assessment, which offers little supporting information. In addition, several other consumer products such as hair and wig glues and gun scrubbers were retained in the conditions of use (Table 2-3). A more comprehensive and detailed accounting of the use or non-use of TCE in consumer products should be included in the draft risk evaluation to justify the exclusion of any conditions of use.	N	N	N	N	N	N	N	N	N	Y	N
561	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Exposure	2.3.2	Releases to the Environment (Section 2.3.2) The total amount of TCE used in consumer products should be calculated and considered to be released to the environment. This TCE volume will end up in the air or groundwater during use or from waste disposal.	N	N	N	N	N	N	N	N	N	Y	N
562	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Exposure	2.3.5.1	Occupational Exposures (Section 2.3.5.1) Under Inhalation, the EPA summarizes regulatory and non-regulatory exposure limits for TCE. It would be appropriate to include the EPA RfC (estimated concentration likely to be without significant risk of harmful effects) for continuous TCE exposure (0.002 mg/m3) in this section. The state of Massachusetts uses this number to derive an occupational guideline of 0.08 mg/m3 (Mass DEP 2014).	N	N	N	N	N	N	N	N	N	Y	N
563	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	PESS	2.3.5.4, 2.4.2.4	Potentially Exposed or Susceptible (Section 2.3.5.4 or Section 2.4.2.4) We suggest including additional populations in EPA's evaluation of risk to highly exposed or susceptible populations. Individuals highly exposed to TCE through past environmental contamination (such as TCE from a subsurface groundwater plume entering a home) should be included on the basis of exposure. These exposures should also be evaluated in combination with exposures from current conditions of use and associated environmental releases. We also direct EPA's attention to the use of TCE in hair extension and lace wig glue. Use of these products may be of particular concern for Black women, who disproportionately suffer from health and environmental justice disparities. There are also groups of individuals who may be more biologically susceptible to the hazards associate with TCE. Individuals with alterations in the CyP2E1 enzyme may have different exposure patterns to TCE or its metabolites (EPA 2011). EPA removed a reference to this possible source of susceptibility that was present in the previous scoping document, and we urge its inclusion in the draft evaluation. Finally, because of TCE's developmental toxicity, EPA must explicitly name pregnant women and fetuses as susceptible populations for occupational, consumer, and general population exposures.	N	N	N	N	N	N	N	N	N	Y	N
564	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Human Health	2.4.2	Human Health Hazards (Section 2.4.2) We support the inclusion of fetal cardiac malformations as the most sensitive endpoint under reproductive/developmental effects. We were pleased to see that EPA retained language supporting the use of animal cancer data to infer human cancer hazard for this evaluation. Finally, we remind EPA of the epidemiological evidence linking breast cancer with TCE exposure. An Italian study of electrical manufacturers found increased odds of breast cancer among women who had ever worked with TCE compared to women with "blue collar" job titles at the plant who had never worked with TCE, and those odds increased when further limited to women who had worked at the factory for more than 10 years (Oddone, Edefonti et al. 2014). Additional epidemiological studies have found positive associations with breast cancer and occupational exposure to TCE (Sung, Chen et al. 2007; Radican, Blair et al. 2008).	N	N	N	N	N	N	N	N	N	Y	N
565	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Exposure	2.5.3.3	Pathways that EPA Does Not Plan to Include in the Risk Evaluation (Section 2.5.3.3) The EPA does not plan to include exposures to the general population or environment arising from release of TCE to air, water, groundwater, or land (including landfills), on the basis that these releases are already adequately assessed and managed by existing environmental statutes. However, existing environmental statutes cannot substitute for evaluation of the risk from these releases in this risk evaluation for three major reasons. First, not all TCE releases are assessed or controlled under these programs. Second, relevant regulations take into account cost and other factors that TSCA cannot legally consider in this portion of the evaluation. Third, the residual risk remaining in the presence of existing regulations has not been comprehensively assessed.	N	N	N	N	N	N	N	N	N	Y	N
566	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Exposure	2.5.3.3	The following are some of the many gaps in TCE management under existing statutes. The EPA cites the Clean Air Act Hazardous Air Pollutant (HAP) as effectively covering emissions to air from stationary sources and Safe Drinking Water Act standards as effectively addressing exposures in drinking water. However, HAP rules are applied on a source by source basis and regulations only exist for some sources. Where regulations do exist, the regulations are often outdated: the most recent Risk Technology Review for Halogenated Solvent Cleaning dates to 2007 (EPA (Environmental Protection Agency) 2007), while a newer review should have been issued in 2015. HAP regulations are also based on cost and energy considerations that are not permitted in TSCA risk evaluations. The National Primary Drinking Water Regulations under the Safe Drinking Water Act cover public water sources, not private wells. For consumer products, very few regulations limit release to the environment.	N	N	N	N	N	N	N	N	N	Y	N
567	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Exposure	2.5.3.3	We strongly encourage the EPA to comprehensively assess all environmental emissions identifying each source, the relevant regulation and resulting reduction in emissions, and estimating residual exposure to the general population and the environment. Importantly, EPA must estimate the total residual exposure in each context separately (for example to the general population from the air, from drinking water, from ground water/subsurface vapor) and in combination from all sources.	N	N	N	N	N	N	N	N	N	Y	N
568	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Exposure	2.3, 2.5, 2.6	Aggregate and cumulative exposures In its response to comments, EPA states that it will consider whether to address aggregate exposure in the next, analysis phase, and has not yet decided whether to assess risk from cumulative exposures. We urge EPA to include both aggregate and cumulative exposure assessments in the risk evaluation.	N	N	N	N	N	N	N	N	N	Y	N

569	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Exposure	2.3	In order to ensure that exposure models and assessments adequately capture, and do not underestimate, exposure, we encourage the EPA to consider aggregate exposures in the following ways: • Consider combined exposures across different routes of exposure (inhalation, oral, dermal) for each population: occupational, consumer, and general. • Calculate an aggregate exposure of consumer exposures that also account for the exposures that individuals encounter as members of the general population. • Calculate an aggregate exposure of occupational exposures that also account for exposures that workers or occupational non-users encounter outside the workplace, as consumers and members of the general population. • General population exposures must include current exposures to TCE from past releases to the environment.	N	N	N	N	N	N	N	N	N	Y	N
570	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Exposure	2.3	Because exposure to TCE co-occurs with other related chemicals, cumulative effects from coexposures to chemicals that act in similar ways should be considered. An investigation of Marines stationed at Camp Lejeune, North Carolina found that the Camp's population was exposed to TCE in drinking water, as well as perchloroethylene (PCE), benzene, and vinyl chloride (Ruckart, Bove et al. 2015). Co-exposure to chemicals that have similar toxic action may act in a dose additive manner. An example of chemicals with similar modes of action considered for dose additive effects and cumulative exposures is phthalates. Concurrent exposures to some phthalates result in a greater effect than exposure to individual phthalates (National Research Council 2008). The Consumer Product Safety Commission prohibits childcare products from containing a group of phthalates that have anti-androgenic activity for their cumulative exposures and effects on the male reproductive system (U.S. Consumer Product Safety Commission 2014). We encourage EPA to investigate toxic activity exhibited by TCE that overlaps with similar activity exhibited by related chemicals with potential co-exposures in order to assess the need for a cumulative risk assessment.	N	N	N	Y	N	N	N	N	N	Y	N
571	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Exposure	2.3	Upper bound exposures We encourage the EPA to consider the maximum or 99th percentile when calculating risk. Maximum values can skew considerably higher than the median or 95th percentile. If an exposure scenario is chosen that doesn't account for the most exposed individuals, many individuals could be left unprotected from TCE's effects. We thank EPA for its attention to these issues, and look forward to reviewing them further in the draft risk evaluation.	N	N	N	N	N	N	N	N	N	Y	N
572	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Exposure	2.3	Upper bound exposures We encourage the EPA to consider the maximum or 99th percentile when calculating risk. Maximum values can skew considerably higher than the median or 95th percentile. If an exposure scenario is chosen that doesn't account for the most exposed individuals, many individuals could be left unprotected from TCE's effects. We thank EPA for its attention to these issues, and look forward to reviewing them further in the draft risk evaluation.	N	N	N	N	N	N	N	N	N	Y	N

Problem Formulation Documents - Public Comments

GENERAL COMMENTS- APPLY TO ALL

#	Submitter	Attachments (#)	Category
1	ACC	3	General
2	ACC	3	General
3	ACC	3	General
4	ACC	3	General
5	ACC	3	General

Document Section #
N/A
N/A
N/A
N/A
N/A

Comment
Section 26 of TSCA mandates that EPA make science-based decisions under Sections 4, 5, and 6 of TSCA in a manner consistent with the best available science and the weight of the scientific evidence. EPA's development of a structured process to identify, evaluate, and integrate evidence from both the hazard and exposure assessments developed during the TSCA risk evaluations is appropriate and will provide increased transparency into the TSCA risk evaluation process.
In general, EPA should make the results of its systematic review process available as part of the docket for each risk evaluation, including its selection of key studies and study quality evaluations.
EPA has identified those conditions of use that will be within the scope of the risk evaluations, as well as those that will be excluded. The risk evaluation rule makes clear that EPA should focus on those conditions of use that raise the greatest potential for risk. ACC generally supports the approach taken to addressing conditions of use within each of the 10 problem formulations. This approach allows EPA to be efficient, while still addressing the highest priority conditions of use that pose the greatest potential risk.
The problem formulation documents present a thoughtful approach to identifying current uses that are appropriate for inclusion within the scope of the risk evaluation. We also appreciate EPA's efforts to explain why the conditions of use that are not within scope will be excluded. ACC encourages continued stakeholder engagement with manufacturers and users of these chemicals throughout the risk evaluation process to ensure the best available information is used.
As EPA gains more experience conducting TSCA risk evaluations for high priority chemicals, it would be useful if the Agency would develop a framework that articulates its process for deciding when conditions of use are in or out of scope. This would help EPA streamline future efforts, provide greater public understanding of EPA's decisions, increase transparency and reproducibility, and enable industry to identify the types of information that may be most helpful for manufacturers, processors, and downstream users to develop and/or share with EPA. Developing a framework would also help industry anticipate which conditions of use will be the likely focus in future assessments so that they can direct resources efficiently to develop and/or gather information relevant to EPA's potential risk evaluations and facilitate proactive data collection efforts.

Applies to ALL (Y/N)	RAD POC	Docket #	Action Needed
Y			
Y			
Y			
Y			
Y			

6	ACC	3	General
7	ACC	3	Exposure
8	ACC	3	Exposure
9	ACC	3	General
10	ACC	3	Exposure
11	ACC	3	General

N/A
N/A
N/A
N/A
N/A
N/A

"Section 9(d) of TSCA imposes a general requirement on EPA to consult and coordinate with other federal agencies for purposes of "achieving the maximum enforcement" of TSCA while imposing the "least burdens of duplicative requirements on those [subject to TSCA]." This Section 9(d) coordination requirement has existed since TSCA was originally enacted and was unchanged by the 2016 amendments. Section 9(d) is a general policy directive that applies to EPA for all TSCA implementation activities. The risk evaluation rule also contains a general consultation provision that codifies the statutory requirement for interagency collaboration during the risk evaluation process." The principle driving this coordination requirement is that EPA should avoid imposing unnecessary or duplicative burdens on regulated entities and avoid regulatory actions best taken by another agency or under other EPA authority. This necessarily includes all manner of Agency interaction with regulated entities, including submission of information, docket management, responses to comments, and other engagement with multiple regulatory bodies. Where non-TSCA regulatory schemes are sufficiently effective at addressing risk, EPA may properly exclude covered conditions of use from the scope of the risk evaluation.
Regarding occupational exposures, EPA should consult early with OSHA in the risk evaluation process—certainly at the earliest stages of the risk evaluation and well before the scope is released. This consultation should continue throughout the risk evaluation. None of the 10 problem formulations make clear what consultation may have occurred, or when it occurred. Although the problem formulations do identify available occupational exposure levels (OELs), i.e., PELs, TLVs, and IDLH values, additional information should be provided regarding the factors EPA will take into consideration when evaluating OELs. For example, consideration should be given to whether the OEL includes current toxicological and epidemiological data to support the development of the threshold limit value. EPA also presents summarized personal monitoring air samples obtained from OSHA inspections, but it is not clear how these data were obtained from OSHA and under what circumstances the data were gathered.
EPA should give preference to direct data obtained for uses being evaluated with consideration given to how the data were gathered (i.e., workplace exposure monitoring data are gathered on a more routine basis while OSHA monitoring is conducted typically in compliance with the OSHA Technical Manual for 8 hours and the sample will generally involve the scenario or tasks in which the highest exposure is expected).
For purposes of 9(d) compliance, it would be helpful if subsequent risk evaluation scopes offer more detail regarding EPA's coordination with other agencies, including information such as consultation plans, data shared, etc. We encourage EPA to include such a coordination plan in future scopes and to include these plans in the draft risk evaluations, including notations where consultation has occurred.
It would be helpful for EPA to describe the decision criteria/framework by which it will evaluate whether to include occupational exposures in the scope of a risk evaluation. This description was not included in the 10 problem formulation documents.
EPA should apply a tiered approach throughout the risk evaluation process–from screening/prioritizing chemicals to conducting risk evaluations–under amended TSCA. This is essential to enable EPA to meet TSCA's statutory deadlines for completing risk evaluations, adhere to TSCA's robust scientific standards, and enable both EPA and the regulated community to apply limited resources efficiently.

Y			
Y			
Y			
Y			
Y			
Y			

12	ACC	3	General
13	ACC	3	Exposure

N/A
N/A

When a screening-level assessment is insufficient to conclude a lack of risk to exposed populations, EPA should take steps to refine the risk evaluation allowing more accurate quantification of potential risks. The scoping/problem formulation documents indicate where the EPA feels it has sufficient information and where additional information and use of higher-tier tools is warranted. In situations where EPA may need to perform higher-tier assessments for the risk evaluation, more information is needed on the types of data and techniques that EPA will utilize. For example, EPA should indicate how probabilistic risk assessment (PRA), uncertainty analyses, and the use of statistical tools such as Bayesian statistics would be used at a higher tier within the overall problem formulation framework. A tiered, iterative approach is critical to the production of high quality risk evaluations based on the best available information.
The value of tiered exposure assessment is well-established. In its 1992 guidelines on exposure assessment,10 EPA discusses the value of tiered exposure assessments from screening-level assessments to more complex assessments. This perspective was reiterated in EPA's 2016 peer review draft update of the 1992 guidelines. The 2016 draft update included specific discussion of considerations in tiered assessments, as well as the notion of "fit for purpose" assessments, stating "[t]he type and purpose of an exposure assessment determine the data and information requirements." The EPA Office of Research and Development (ORD) ExpoBox tool box for exposure assessors identifies exposure assessments tools by tier and type, both screening-level and refined, for planning, scoping, and problem formulation. The purpose of tiered exposure approaches is well understood: to identify uses of chemicals that, under very conservative (e.g., maximum) exposure assessment assumptions, are not likely to pose a health risk. Depending on the conditions of use, the exposure assessment information can be used either to identify a chemical as a low priority or to be factored into the overall risk evaluation. Exposures that initially exceed hazard benchmarks in Tier-1 exposure assessments would require more refined, higher-tiered approaches to exposure assessments. This would include the application of more realistic parameters related to the likely duration, intensity, frequency, and number of exposures and more realistic exposure scenarios to more accurately quantify actual risks of the chemical. The importance of EPA using a tiered approach to exposure assessment in its TSCA risk evaluations cannot be overstated. A tiered approach allows for both a more rapid, yet systematic, approach for assessing conditions of use in a first-tier screen, so that resources are used effectively when a refined exposure assessment is necessary for those conditions of use that do not "pass" a first-tier screen. well-defined, tiered exposure approach can lead to greater efficiencies in chemical risk evaluations under TSCA. Congress clearly valued such efficiency highly as evidenced by the aggressive deadlines it set for EPA to conduct TSCA risk evaluations. Congress also directed the Agency to consider the likely duration, intensity, frequency, and number of exposures under the conditions of use.

Y			
Y			

14	ACC	3	Exposure
15	ACC	3	Exposure
16	ACC	3	Exposure

N/A
N/A
N/A

The value of tiered exposure approaches in risk evaluations is even broader than exposure assessment. This was discussed in the Health and Environmental Sciences Institute's (HESI) Coordinated Risk Assessment in the 21st Century (Risk21) project. A review article published in 2014 discussing Risk21's principles and framework for decision-making in human health risk assessment emphasizes that problem formulation for risk assessment should not be a hazard-driven process, but instead should start with exposure, focusing on exposure scenarios of greatest concern integrated with hazard information to support risk-based decision making. The article suggests this approach would result in an early estimate of potential human exposure in relevant populations, including susceptible populations, which would characterize the degree of specific toxicological data needs. The Risk21 framework also addresses two other principles: (1) additional data should be acquired "only if necessary and when they add value" and (2) flexibility, "such that a higher tier hazard assessment approach can be coupled with a lower tier exposure approach, and vice versa." Considerable progress has been made over the last several years in developing screening-level exposure prediction models for chemicals in commerce. These approaches can be of particular utility in conducting Tier-1 assessments for many chemicals. In the context of TSCA's risk evaluations, tiered-assessment concepts equip EPA with the tools it needs to meet TSCA's aggressive deadlines for completing risk evaluations of high priority chemicals. Tiered assessments also enable EPA to apply limited resources in an efficient manner. Using a clear, science-based tiered-assessment approach, EPA and the regulated community can perform exposure assessments in TSCA risk evaluations, enabling efficient decision-making.
The draft problem formulation documents of the initial 10 chemicals mention the Agency's plans to use tiered exposure assessments in its risk evaluations of these chemicals, but the documents lack specifics. A clear "road map" showing EPA's approach to tiered exposure assessments is needed in EPA's scoping documents. Such a road map—or decision tree—would provide structure to EPA's approach to exposure assessments under TSCA. This structure would also be useful to explain how EPA will integrate the results of its tiered exposure assessments with the results from its tiered-hazard assessments in TSCA risk evaluations. A road map would signal to the regulated community the type of reasonably available exposure information EPA plans to rely upon, what additional exposure information might be needed, and what actions manufacturers could take early in the risk evaluation process to provide EPA the needed exposure information. EPA should delineate what kinds of data and information it could accept to refine lower-tier exposure assessments.
Specifically, with respect to potential human exposures in the problem formulation documents, EPA should identify: -The screening-level exposure information/models EPA will use to address human exposure in Tier-1 exposure assessments; -The approach to hazard characterization and threshold EPA will use to ascertain the need for a higher-tier exposure assessment; -How EPA will communicate Tier-1 exposure screening-level results; -The higher-tiered information and models EPA will use to address human exposures, suggested by the results of the screening-level information/models; -How EPA might use tiered exposure evaluations for specific exposure scenarios (e.g., occupational, consumer, residential, etc.); -What kind of data and information EPA would accept (i.e. from stakeholders) to refine a Tier-1 screening exposure assessment.

Y			
Y			
Y			

17	ACC	3	Exposure
18	ACC	3	Exposure
19	ACC	3	Exposure
20	ACC	3	Exposure

N/A
N/A
N/A
N/A

TSCA Section 26(l) requires EPA to develop "policies, procedures and guidance that the Administrator determines are necessary to carry out the amendments" of amended TSCA. EPA indicates its intent to use tiered approaches in TSCA risk evaluations, but guidance is needed. EPA should develop new, more specific guidance on its plans to use tiered approaches to exposure assessment in TSCA risk evaluations. In doing so, EPA must move beyond mere "concepts" and reference lists to specific information, models, and tools. As stated earlier, EPA should indicate how PRA, uncertainty analyses, and the use of statistical tools would be integrated as a higher tier assessment. Specific and transparent guidance is needed to understand how the Agency will conduct its exposure assessments so that manufacturers can provide the most relevant information early on in the process to the Agency and so that stakeholders understand the process. As stated earlier, EPA should indicate how PRA, uncertainty analyses, and the use of statistical tools would be integrated as a higher tier assessment. Such guidance will also allow stakeholders to provide additional information to refine initial lower tier exposure estimates. Further program-specific guidance is also needed for those manufacturers that plan to conduct risk evaluations for EPA's consideration and must conform to EPA's approach to risk evaluations should they do so. Guidance on tiered approaches will help streamline the risk evaluation process under TSCA and enable EPA to meet TSCA's new mandates.
Canada's Chemical Management Plan (CMP), Australia's Inventory of Chemical Substances,23 and the EU's Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) program24 employ tiered approaches in their exposure assessment approaches for chemicals. EPA should review those approaches to ascertain their usefulness in new EPA guidance on tiered exposure assessments in TSCA risk evaluations.
According to EPA's problem formulations, EPA plans to further analyze occupational exposures in nine of the 10 chemicals risk evaluations. EPA must be more transparent about its coordination with OSHA regarding its plans to address occupational exposure issues in TSCA Section 6 risk evaluations. The methods, models, and databases that the Agency uses to conduct its occupational exposure assessments must be adequate to satisfy TSCA's Section 26 standards for best available science and weight of the scientific evidence. EPA should be more transparent about the OSHA and NIOSH databases that EPA plans to rely upon in these risk evaluations. Greater transparency will provide manufacturers notice about the type of information EPA may not have, but may need, to conduct a realistic occupational exposure assessment.
In eight of the problem formulation documents, EPA has identified OSHA's Chemical Exposure Health Data (CEHD) and NIOSH's Health Hazard Evaluation (HHE) program data as two major sources of occupational monitoring data that it will rely upon in the risk evaluations. However, EPA does not discuss what information in these databases it plans to rely upon; how representative the data are; what criteria EPA will use in deciding which data are or are not applicable for its exposure assessments; or how it plans to assess those data in the context of current OSHA regulations and industrial hygiene practices. EPA must provide greater detail about its use of the information in these OSHA and NIOSH databases to enable stakeholders to comment upon the data quality for the purposes for which EPA plans to rely upon the data, and to provide the Agency higher quality data where it exists.

Y			
Y			
Y			
Y			

20 cont	ACC	3	Exposure
21	ACC	3	Exposure
22	ACC	3	Exposure

N/A
N/A
N/A

For instance, it is our understanding that the OSHA CEHD information does not include a description of the activities associated with the specific exposure measurements. Without this information, how will EPA be able to apply these results to the conditions of use identified for a chemical? Absent sufficient knowledge of activities associated with occupational exposure measurements, EPA might very well improperly assign exposure values to a certain condition of use/application. This could result in inappropriate conclusions about risk under specific conditions of use or risk management recommendations for protection of workers. It appears that this database reports non-detects (ND), but it does not specify the limit of detection (LOD). Without an understanding of the accuracy of the data, how will EPA use this data to inform estimates of exposure? In occupational settings, potentially hazardous exposures are eliminated or minimized by the use of training, industrial hygiene programs, engineering controls, closed systems, personal protective equipment (PPE), labeling, medical surveillance, etc. Over the past several decades, these engineering and industrial hygiene practices have continually improved. For example, as part of ACC's Responsible Care® Program, ACC member companies must implement ACC's Process Safety Code, which aims to supplement existing process safety requirements contained within the Responsible Care Management System® and RC14001® technical specifications. The Process Safety Code is intended to complement regulatory standards that, by necessity, focus on process safety at an individual facility. Another concern with the OSHA CEHD database is that much of the data were developed during inspections of facilities suspected of having high employee exposures. This suggests these data are not representative of occupational exposures from facilities that are in compliance with OSHA standards. EPA should address this fact in its quality review of the data/information underpinning its risk evaluations.
ACC understands that some ACC members have provided EPA with occupational monitoring information for use by the Agency in problem formulations for some of the initial 10 chemicals, but this information was apparently not reflected in the problem formulations issued on June 11, 2018. EPA should be clear in the draft risk evaluations how such submitted occupational monitoring information was used to prepare the problem formulations and considered in the risk evaluation.
EPA indicates it plans to further analyze occupational exposures in the draft risk evaluations in nine of the 10 problem formulations. EPA has conducted very few worker exposure assessments on existing TSCA chemicals in the past and its Exposure Factors Handbook does not address occupational exposures.EPA has occupational exposure tools that are designed for specific purposes. For example, ChemSTEER was developed as a conservative screening tool used to estimate workplace exposures and environmental releases for new chemicals that are manufactured and used in industrial/commercial settings. However, broad guidance is not currently available for evaluating occupational exposures under TSCA, in particular with respect to the evaluation of existing chemicals. EPA should develop new guidance for evaluating occupational exposures under TSCA. To develop this guidance, EPA should certainly consider its own information, models, and tools on occupational exposure. EPA should also update some of its older tools and methods to evaluate worker exposure. EPA should update its 1997 Generic Scenarios for industry-specific workplace release and exposure estimation to make certain they reflect current industry practice. Many industrial practices in use today go beyond the legal regulatory requirements of OSHA. EPA should consider current industrial hygiene practices as part of the conditions of use of manufacturing. Additional Generic Scenarios may need to be developed to cover conditions of use for which Generic Scenarios do not currently exist.

Y			
Y			
Y			

23	ACC	3	Exposure
24	ACC	3	Exposure
25	ACC	3	Exposure
26	ACC	3	Exposure
27	ACC	3	Exposure
28	ACC	3	Exposure
29	ACC	3	Exposure
30	ACC	3	Exposure

N/A
N/A
N/A
N/A
N/A
N/A
N/A
N/A

It is also critical that EPA consider other information and tools available from OSHA, from the American Industrial Hygiene Association (AIHA), and from other jurisdictions to develop new occupational exposure guidance for TSCA purposes. EPA should consider the applicability of new models being used in Canada and the EU in their chemical regulatory programs. In considering information and tools from OSHA, AIHA, and other jurisdictions, EPA should also consider the adequacy and appropriateness of use of those tools in the TSCA context.
With respect to dermal exposures, the problem formulation documents identify several models for application to four of the 10 chemicals. EPA's existing dermal exposure assessment guidance is primarily geared toward neat compounds in soil or water, and it is not clear whether this guidance is sufficient to evaluate chemicals encountered in industrial-use scenarios.
For inhalation exposures, EPA has identified several models it plans to use in nine of the problem formulations. EPA guidance on potential inhalation exposures in occupational conditions of use under TSCA would be helpful.
Guidance on occupational exposure assessment under TSCA should address how the Agency will consider standard industrial hygiene practices as well as how that information will be incorporated into its exposure assessments and how ultimately that information will be integrated into the risk evaluation. EPA should address and identify the specific information the Agency will need to accomplish these steps; the level of detail needed to enable the Agency to reach a determination about the adequacy of design measures such as: closed systems; the use of engineering controls and labeling requirements (e.g., the use of gloves or other PPE); and other operating procedures and management practices currently in use to eliminate or adequately minimize exposures in occupational settings. EPA should describe how these considerations are incorporated into a tiered occupational exposure assessment.
EPA may need to gather information from industry regarding current occupational exposure protection practices. Industry may be able to facilitate access to that information. Manufacturers and organizations like AIHA may be able to help the Agency gather information about exposure data in occupational settings and industrial hygiene practices in various workplace situations. Ultimately, through such efforts, an EPA exposure factors handbook for occupational exposures could potentially be developed to address TSCA risk evaluation needs.
Consistent with application of a tiered approach to assessing exposure, EPA should articulate what kind of data will be acceptable to refine an initial lower tier occupational exposure assessment. For example, if a screening level estimate from ChemSTEER needs to be refined, a road map (as described above) would be a key element of guidance to develop the necessary information to conduct a higher tier assessment.
EPA should be more transparent about specific exposure models, margins of exposure and occupational exposure limits that it intends to utilize during the risk evaluation process. This will allow stakeholders to provide the Agency the exposure information it needs and can lead to better understanding as to how EPA will make risk determinations.
ACC agrees with EPA's support for using tiered approaches generally, and in exposure modeling in particular. Under a tiered, iterative approach, screening-level tools, which are "protective by design," may be used initially. For substances that appear to present potential risks following a screening-level assessment, EPA should then proceed to use higher-tier tools. By beginning with screening-level assessments—which use more conservative assumptions and information than higher tier models—the Agency can optimize resource allocation by identifying exposure routes that present less risk early in the assessment process. When a Tier-1 screening assessment indicates low risk for a particular condition of use, the Agency should have a high degree of confidence that the potential risks are lower or perhaps nonexistent.

Y			
Y			
Y			
Y			
Y			
Y			
Y			
Y			

31	ACC	3	Exposure
32	ACC	3	Exposure
33	ACC	3	Exposure
34	ACC	3	Exposure
35	ACC	3	Exposure
36	ACC	3	Exposure

N/A
N/A
N/A
N/A
N/A
N/A

It is critical that EPA establish clear and consistent guidance that defines when Tier-1 model results will trigger more detailed and refined subsequent assessments. In the problem formulation documents, EPA frequently cites regulatory and non-regulatory occupational exposure limits, but it neither clarifies how it would apply these limits during an exposure assessment, nor specifies a process that will be followed should the Tier-1 model results exceed these limits or margins of exposure. In the event that EPA uses threshold triggers for Tier-2 models within EPA's risk assessment process, the Agency must provide guidance regarding how it selects these values and provide stakeholders an opportunity to comment.
Similarly, EPA should specify which exposure models—for all routes and populations—it intends to use during the risk evaluation process. In the problem formulations, EPA mentions several different models, but it does not provide rigorous guidance as to which tools will be used under which circumstances. Similarly, EPA does not identify specifically what it considers to be "higher tier models." Exposure models vary in terms of the purposes for which they are used, their input requirements, and assumptions. By providing a rationale for its model selection, the Agency will afford stakeholders an opportunity to provide appropriate data and contribute relevant information to EPA during its risk evaluations.
EPA also should be clear about the use of modeled vs. measured data in evaluating exposure. For example, if measured data are rejected in favor of modeled estimates, the rationale for such a decision needs to be clear.
EPA participates in the OECD's Working Party on Exposure Assessment (WPEA). In that capacity, EPA has been a global leader helping harmonize chemical use categories and developing standard exposure/emission scenario documents (ESDs) for occupational exposure assessments for chemical regulations. ACC expects that EPA will use these standard exposure scenarios in its occupational exposure assessments, but that is not clear from the problem formulation documents. EPA should clarify this point in its draft risk evaluations of these 10 chemicals and in any new guidance the Agency develops on exposure assessments under TSCA.
In addition, EPA should develop additional standard exposure scenarios for both worker and consumer exposures under TSCA. Standard exposure scenarios would assure greater consistency in EPA exposure assessments; improve exposure model parameters; and help industry understand what specific information EPA needs in exposure assessments for TSCA risk evaluations. In short, standard exposure scenarios would improve efficiencies when conducting TSCA risk evaluations, which are critical given TSCA's statutory deadlines. EPA may want to consider stakeholder workshops to discuss ways in which standard exposure scenarios might be developed in the US. If so, EPA should also ensure that standard scenarios developed under REACH be discussed and considered at such workshops since many of these may be useful in TSCA as well.
EPA Should Explain What Additional Ecological Exposure Assessment Tools Are Available. The screening-level approaches described in the problem formulation documents are appropriate for this step (i.e., E-FAST), but EPA should identify acceptable tools/methods for higher-tier refinement when necessary. Screening-level exposure analysis may be suitable in cases where estimates do not exceed the Concentration of Concern (COC). EPA should explain how it would use higher-tier information, if provided.

Y
Y
Y
Y
Y
Y

37	ACC	3	Exposure
38	ACC	3	Exposure
39	ACC	3	Exposure
40	ACC	3	Exposure
41	ACC	3	Exposure
42	ACC	3	Exposure

N/A
N/A
N/A
N/A
N/A
N/A

EPA has indicated that environmental exposure data may be available for some of these 10 chemicals in the EPA Discharge Monitoring Report tool, EPA's STOrage and RETreival (STORET) system, USGS National Water Quality Assessment (NAWQA) program, and other sources. Some of these data sources may not be current and therefore may not represent the best available information. EPA should clarify exactly how it would use such data to establish a national, regional, or local environmental exposure estimate.
EPA should also clarify how it will quantify and assess (or exclude) naturally-occurring sources of chemicals for assessment during exposure estimation.
EPA's Consumer Exposure Model (CEM) is mentioned as the preferred tool for estimating consumer exposures in several of the first 10 chemicals' risk evaluations. This model is publicly available. However, another model mentioned by EPA is the Multi-Chamber Concentration and Exposure Model (MCCEM). This model is available on EPA's exposure tools website, but in a version (Windows 95 operating environment) that will not run on currently available platforms. EPA should ensure that all the models it uses in its assessments are publicly available in a form that is accessible to the general public, complete with explanations on how to use the model and how the exposure endpoints are estimated.
The problem formulations for most of the 10 chemicals indicate that the chemical is found in either formulated products used by consumers or in articles with which consumers could come into contact. It is not clear how EPA will assess consumer exposures to these products. The exposure assessments must be able to estimate the consumer exposures from these chemicals based on whether they are found in formulated products or articles.
For chemicals that are primarily in articles, the approach and rationale for estimating consumer exposures should be described in detail because exposure assessments from articles are a new area of assessment. Industry and other stakeholders may not be familiar with the rationale and approaches used to estimate exposures from articles. The scientific basis for determining exposures from chemicals in articles must be established for the Agency to meet the statutory standard that requires TSCA risk assessments to quantify the likely (i.e., having a high probability of being true) duration, intensity, frequency, and number of exposures under the conditions of use. EPA should clearly identify the criteria for and scope of the tools chosen to be used in each circumstance.
For exposure assessments, EPA may need to make decisions about which products to focus on in the assessments among the various potential products in which the chemical may be found. To conduct the consumer exposure assessment, the assessor may need to focus on representative products in some of these use categories. The product types chosen to be used in the exposure models, the exposure routes, most relevant exposure scenarios, exposure endpoints, and rationale for the choices must be described. The greater the clarity and transparency of these explanations, the greater the likelihood the final assessment will be understood.

Y
Y
Y
Y
Y
Y

43	ACC	3	Exposure
44	ACC	3	Exposure
45	ACC	3	Human Health
46	ACC	3	Human Health

N/A
N/A
N/A
N/A

EPA states in several of the problem formulations that TRI data will be used as a source of information on releases to the environment. TRI data may have a role to play as an element in chemical prioritization, but these data also have limitations. EPA states on the TRI website: [The Toxics Release Inventory (TRI) provides data about environmental releases of toxic chemicals from industrial facilities throughout the United States, measured in pounds. The quantity of releases, however, does not indicate the level of health risk posed by the chemicals. Although TRI data can't tell you whether or to what extent you've been exposed to these chemicals, they can be used as a starting point in evaluating potential risks to human health and the environment.] EPA readily acknowledges in its TRI National Analysis 2016: Releases of Chemicals that "[h]uman health risk resulting from exposure to toxic chemicals are determined by many factors..." These factors include environmental fate, individual exposures, chemical properties, and concentration, none of which are furnished through the TRI. For a chemical to present a risk, there must be a sufficient pathway and exposure, factors that TRI does not address. EPA should acknowledge and explain the limited value of TRI data in risk evaluation.
Biomonitoring information is identified in several of the problem formulations as a type of data/information source for TSCA risk evaluations, but there is limited discussion of how or where it would be used. EPA should address in guidance the specific biomonitoring information it would rely upon in TSCA risk evaluations and how it would be used. Canada uses "biomonitoring equivalents" in its risk assessments under the Canadian Management Plan (CMP). EPA should examine how those values, as well as Canada's assessments that are based upon them, might be used in the TSCA exposure assessments.
It is important that a multidisciplinary review process, which integrates hazard information and data from in vitro and in vivo studies across different biological levels of organization for a given exposure scenario, be established for hazard evaluation, data review, and decision making contexts. Typically, this should be a transparent and structured analysis using the Bradford Hill causal considerations and, in particular, biological plausibility and empirical support (dose response, temporal concordance and consistency). The hazard information must be relevant to the specific exposure scenario and the integration of data should be applied initially for each data stream (epidemiology, in vivo, mechanistic) across similar types of study endpoints. The lines of evidence (human epidemiology, in vivo toxicity and mechanistic) must then be integrated using a transparent and objective approach. Through such an integrated assessment, evaluators use the entire body of studies and the full weight of the scientific evidence. This approach avoids the pitfalls of selecting the lowest statistically significant finding of a response in a given study (as a default) without adequately framing the risk hypotheses and integrating data from different sources. EPA states in the general response to comments on the initial 10 scope documents that it anticipates using data from alternative test methods for the risk evaluations. This is consistent with the mandate under TSCA Section 4(h) to "reduce and replace, to the extent practicable, scientifically justified, and consistent with the policies of this title, the use of vertebrate animals in the testing of chemical substances or mixtures..."
ACC supports EPA's continued efforts to identify, develop, and integrate new approach methodologies (NAMs) for regulatory decision-making according to the EPA OPPT Strategic Plan to Promote the Development and Implementation of Alternative Test Methods. It is important that sufficient scientific confidence in each NAM be established for its intended application before use as a key piece of evidence in a hazard evaluation and limitations be acknowledged. It is equally important that exposure information, at a fit-for-purpose level of resolution, is available to place these data into a risk context.

Y
Y
Y
Y

47	ACC	3	Human Health
48	ACC	3	Human Health
49	ACC	3	Human Health

N/A
N/A
N/A

EPA acknowledges that it must further analyze the MOA for cancer risk in the problem formulations. ACC supports that analysis. The AOP framework is a tool to systematically organize available data and knowledge that describes scientifically plausible and causal relationships across multiple levels of biological organization between a molecular initiating event (MIE) and subsequent key events (KEs), culminating in an adverse outcome (AO) potentially relevant to risk assessment. EPA researchers have been instrumental in developing AOPs and tools to facilitate the further development, review, and use of AOPs in scientific and regulatory endeavors. Tools such as the AOP wiki can be mined for additional data and organizational principles as well as domains of applicability for various identified MOAs associated with chemicals. Thus, whether evidence generally aligns or does not align with any proposed or known MOAs and/or AOPs should be a necessary consideration in integrating evidence to reach conclusions.
The Agency's focus on dose-response data and models reflects the fact that toxicology has evolved over the past 35 years from a largely observational field of study to a discipline that applies advanced scientific techniques and knowledge to investigate how chemicals interact with biological systems at the molecular, cellular, organ, and organism levels to understand the biological basis for the induction of toxicity. As a consequence of rapid advances in scientific understanding and the application of this knowledge to regulatory science policy and risk assessments, risk assessors can now evaluate biological events leading to toxicity and consider how, in a dose-response manner, these events relate to potential risks to human health. Despite the significant progress, movement away from default assumptions has been slow to occur, particularly in certain EPA programs. Failure to recognize and act on advances in scientific knowledge and the best available, most relevant scientific data and dose response models wastes significant research and development investments. It is also contrary to the TSCA Section 26 requirement that EPA rely upon best available science in science-based Section 6 decisions.
In its 2005 Cancer Guidelines, EPA is clear that when risk assessments are performed using only one set of procedures, it may be difficult for risk managers to determine how much health protection is built into a particular hazard determination or risk characterization. EPA's Cancer Guidelines state:[When there are alternative procedures having significant biological support, the Agency encourages assessments to be performed using these alternative procedures, if feasible, in order to shed light on the uncertainties in the assessment, recognizing that the Agencymay decide to give greater weight to one set of procedures than another in a specific assessment or management decision.] In addition, the Agency says: [If critical analysis of agent-specific information is consistent with one or more biologically based models as well as with the default option, the alternative models and the default option are both carried through the assessment and characterized for the risk manager. In this case, the default model not only fits the data, but also serves as a benchmark for comparison with other analyses. This case also highlights the importance of extensive experimentation to support a conclusion about mode of action, including addressing the issue of whether alternative modes of action are also plausible.] These statements are related to comment 50.

Y
Y
Y

50	ACC	3	Human Health
51	ACC	3	Human Health
52	ACC	3	Human Health

N/A
N/A
N/A

EPA's Office of Pesticide Programs (OPP) has adopted the World Health Organization (WHO)/International Programme on Chemical Safety (IPCS) MOA framework for organizing, evaluating, and integrating hazard and dose response information. The same approach should be adopted for TSCA assessments. The MOA framework can be used to illustrate the key events in a known toxicity pathway to address whether a reported statistically-significant response is consistent with what is expected based upon knowledge of the biological responses comprising the pathway. It should be noted that even if early biological responses/perturbations are detected, these observations are not necessarily adverse or precursors to adverse effects in living organisms because of adaptive or homeostatic mechanisms. To reliably predict toxicity, key events need to be causally linked to adversity with a clear understanding of dose response/temporal key event relationships. EPA should adopt and use the standard MOA templates for both cancer and non-cancer endpoints, such as the dose/temporal concordance and species concordance templates. These templates have been incorporated by the European Chemicals Agency (ECHA) in implementing Europe's REACH program.
Because the scientific justification for assessing human relevance and selecting dose-response extrapolation methods for quantifying risks at environmentally relevant levels of exposure is highly dependent upon the determination of the likely operative MOA, the Agency should implement a uniform, systematic and explicit approach for evaluating a chemical dataset, using hypothesized MOAs and the evolved Bradford Hill causal considerations, to integrate evidence and derive weight of the evidence (WOE) confidence scores for potentially relevant MOAs. This approach enables a side-by-side comparison of numerical WOE confidence scores for different hypothesized MOAs, including the default linear-no-threshold model, which permits better identification of the likely best MOA to use. The side-by-side quantitative MOA WOE confidence scoring method enhances transparency and improves communication amongst risk managers and the public. Furthermore, the best available science approach provides a transparent, scientifically sound justification for using the most likely operative MOA as the basis for selecting the most appropriate extrapolation method that corresponds to that MOA to then calculate potential risks to humans for environmentally relevant exposures.
To illustrate this method, a case example has been developed based on data of rodent liver tumors induced by carbon tetrachloride (Attachment B-attached in the ACC coments on Problem Forumulation 46 August 2018). This case example used data and lines of evidence from previously published review articles, and relied on those authors' evaluations of the quality of the empirical evidence. Two hypothesized MOAs were evaluated: 1) induction of rodent liver tumors via a mutagenic MOA; and 2) induction of rodent liver tumors via a cytotoxicity MOA. The quantitative MOA WOE confidence scoring results of this case example indicate: (1) it is highly unlikely that carbon tetrachloride induces rodent liver tumors via a mutagenic MOA and (2) Cytotoxicity and sustained regenerative cellular proliferation is the like operative MOA for induction of liver timors in rodents by carbon tetrachloride; there are significant mechanistic data to support thos non-linear, non-mutagenic MOA. Based on the comparison of quantitative MOA WOE confidence scores, there is strong scientific support for using a threshold extrapolation approach for evaluating the cancer risks of carbon tetrachloride. (In contrast, scientific justification is lacking to support a linear, no threshold extrapolation method for evaluating its cancer risks.)

Y
Y
N

53	ACC	3	Human Health
54	ACC	3	Eco Health
55	ACC	3	Eco Health
56	ACC	3	Eco Health
57	ACC	3	General
58	APHA	1	Exposure

N/A
N/A
N/A
N/A
N/A
N/A

Finally, another challenge in extrapolating animal data to human data involves having an understanding of the relative toxicokinetics. Significant strides have been made using physiologically based pharmacokinetic (PBPK) data and models in risk assessment to improve the accuracy of deriving dosimetry considerations. However, it is important to recognize that some animal studies using conventional maximum tolerated doses (MTDs) are flawed and cannot be used to extrapolate to human doses because they exceed the kinetically-derived maximum dose (KMD). In a number of cases, substances show dose-dependent transitions in their mechanisms of toxicity. This circumstance needs to be evaluated appropriately.
EPA has used a simple approach to calculate the acute and chronic COCs, i.e., dividing the lowest study value by an assessment factor. Conservative, screening-level approaches, such as those utilized in the EPA's New Chemicals Program, can be appropriate to provide context at the problem formulation stage. However, in future scoping documents EPA should clarify the circumstances under which further, higher-tier evaluation would be triggered, if necessary (e.g. species sensitivity distribution, etc.).
EPA should identify more sophisticated higher-tier approaches it may use for determining a hazard threshold, especially for data rich chemicals. Toxicity information, and when available, knowledge of mechanisms, are integrated with exposure-response models for risk-based environmental safety decision making. Within an environmental context, the assessment of safety does not end at the organism, but includes extrapolation to populations, communities, and ecosystems. For ecological risk assessment, the possibility of obtaining site-specific population data is a critical option for higher-tier assessment.
EPA should also consider the unique physico-chemical properties that can impact substances' pharmacokinetics and toxicity profiles, as well as their environmental fate and distribution.
Conclusion: ACC commends EPA on its efforts to gather the best available information for the problem formulation documents for the initial 10 chemicals undergoing risk evaluation under amended TSCA. EPA has demonstrated some screening-level assessment techniques that allow EPA to focus on the conditions of use that pose the greatest potential for risk. However, in situations where EPA may need to perform higher tier assessments for the risk evaluation, more guidance and information is needed on the types of data and techniques that EPA will utilize. This will enable industry to better understand how to provide EPA with the information it needs to perform high quality risk evaluations.
TSCA is EPA's primary source of authority for evaluating and managing the health and environmental risks presented by approximately 85,000 industrial chemicals. Unfortunately, the problem formulation documents indicate that the agency intends to conduct risk evaluations that are incomplete and likely to underestimate risk. Specifically, the agency plans to ignore numerous exposures to these chemicals. By considering only some exposures and not others, EPA likely will conclude that the total level of exposure to a chemical is lower than it truly is. The agency then may determine incorrectly that this lower level of exposure does not present an unreasonable risk of injury to health or the environment, even when the true level of exposure does present such a risk. The decision to ignore chemical exposures is unlawful and lacks scientific credibility. EPA should include all exposures to these chemicals in its risk evaluations.

Y
Y
Y
Y
Y
Y

59	APHA	1	Exposure
60	APHA	1	Exposure
61	APHA	1	Exposure
62	APHA	1	Exposure
63	APHA	1	Exposure
64	APHA	1	Exposure
65	APHA	1	Exposure
66	APHA	1	Exposure

N/A
N/A
N/A
N/A
N/A
N/A
N/A
N/A

EPA's problem formulation documents indicate several ways in which the agency intends to ignore exposures to the chemicals. First, TSCA requires EPA to "conduct risk evaluations...to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment...under the conditions of use." TSCA § 6(b)(4)(A) (emphasis added). In general, "the conditions of use" of a chemical include the manufacture, distribution in commerce, processing, use, and disposal of the chemical. EPA has decided to ignore conditions of use and resulting exposures, either by declaring that certain activities are not conditions of use or by acknowledging that the activities are conditions of use but nonetheless declaring that they will not be included in the risk evaluation. These actions by the agency lack both legal and factual support.
Second, EPA has decided to exclude entire exposure pathways, such as inhalation of a chemical in ambient air or ingestion of a chemical in drinking water, from the risk evaluations. These exclusions rely on a flawed analysis of TSCA and other environmental statutes. Furthermore, EPA admits the exclusions will disregard important risks of injury to health.
The exclusion of certain activities from the risk evaluations is unlawful. As noted above, TSCA requires EPA to evaluate the risks presented by "a chemical substance" under "the conditions of use." The language of the statute clearly directs the agency to evaluate the risk presented by a chemical substance in total and does not provide for picking and choosing among conditions of use when conducting a risk evaluation. Even if EPA did possess the authority to include only some conditions of use and not others, however, the agency still has failed to support its exclusions with information provided in the problem formulation documents.
In many cases, it appears that EPA has obtained information via unverified communications with companies that once engaged and still may be engaged in activities that constitute conditions of use. These include manufacturers, processors, distributors, commercial users, and companies involved in disposal of one or more of the chemicals. It does not appear that EPA has taken meaningful steps to verify information provided by companies or their representatives. This is inappropriate due to the obvious conflicts of interest with respect to risk evaluations for chemicals that once were or still are important to their businesses.
For example, EPA has concluded that "domestic manufacture of HBCD has ceased" based primarily on assurances provided by two recent manufacturers of the flame retardant. The agency does not indicate how it verified these assurances or how it will ensure that the purported cessation will continue in the future.
EPA relies on information from entities even after concluding that the information is not credible.
Even if the information provided by a company is accurate, the company remains free to resume any activity at any point in the future absent a regulation stating otherwise. Such an activity therefore remains a "reasonably foreseeable" condition of use under the statute. Furthermore, accurate information that may be provided by one company or subset of companies cannot be assumed to represent the activities of all current or future firms within an industry. Yet EPA makes this assumption.
At a minimum, if EPA is told that manufacture, import, and processing of a chemical has ceased, the agency should demand legally binding certification of such cessation from every previous manufacturer, importer, and processor of the chemical. Furthermore, the agency should promulgate a significant new use rule under TSCA § 5(a) so that, if and when manufacture, import, or processing of the chemical does occur in the future, the activity must be reported to EPA.

Y
Y
Y
Y
N
Y
Y
Y

67	APHA	1	Exposure
68	APHA	1	Exposure, RegNex
69	APHA	1	Exposure, RegNex
70	APHA	1	Exposure
71	APHA	1	PESS

N/A
N/A
N/A
N/A
N/A

In addition to ignoring conditions of use, EPA intends to disregard entire pathways of exposure to chemicals. By disregarding these pathways, EPA will narrow the scopes of the risk evaluations further. In addition, for every chemical except pigment violet 29, EPA argues it can ignore exposures resulting from disposal. By excluding pathways, the agency will ignore potential exposure to more than 68 million pounds of industrial chemicals released each year. EPA's rationale for excluding pathways disregards TSCA and, by the agency's own admission, ignores unreasonable risks of injury to health.
According to the agency, exposure pathways will be excluded when they fall under "other environmental statutes, administered by EPA, which adequately assess and effectively manage exposures and for which long-standing regulatory and analytical processes already exist[.]" There are key differences between the requirements imposed by "other environmental statutes" and the requirements imposed by TSCA.
EPA is required to evaluate the risk presented by chemicals under TSCA. This includes any risks to vulnerable populations. The agency cannot escape this requirement by ducking behind unrelated statutes that impose separate requirements to protect public health.
EPA admits that excluding exposure pathways will neglect unreasonable risks of injury to health presented by the chemicals.
TSCA requires EPA to determine whether a chemical presents an unreasonable risk of injury to the general population and/or to "potentially exposed or susceptible subpopulations." §6(b)(4)(A). A potentially exposed or susceptible subpopulation is any "group of individualswithin the general population...who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population...such as infants, children, pregnant women, workers, or the elderly." § 3(12). It is well understood, for example, that pregnant women, children, and infants are uniquely susceptible to chemical exposures. TSCA imposes a duty on EPA to ensure that vulnerable subpopulations are protected from chemical risks, and it is imperative that the agency conduct risk evaluations, make risk determinations, and promulgate risk management regulations in accordance with this duty. In particular, TSCA provides new tools to protect workers from occupational exposures to a wide variety of chemicals encountered while on the job. Workers face significant risk of harm from chemical exposures but they are not adequately protected by regulations of the Occupational Safety and Health Administration. OSHA has adopted comprehensive health standards on just a few dozen chemicals since the agency was established in 1971, and most of these standards were issued before 1990.25 Furthermore, tens of millions of workers are not covered by the Occupational Safety and Health Act. EPA's duty to protect workers and other vulnerable subpopulations under TSCA fills in gaps in the law that have allowed workers to go unprotected from chemical hazards.

Y
Y
Y
Y
Y

72	NTTC	1	Exposure, General
73	NTTC	1	PESS, General, Exposure
74	NTTC	1	General, Exposure

N/A
N/A
N/A

Beyond the clear primary issue to Tribes of the absence of tribally-specific risk scenarios in the problem formulation, NTTC further takes issue with the following critical points that relate to the problem formulations in general and prevent the performance of a valid health assessment for tribes and other Americans as intended by Congress: -Omission of legacy use, particularly the use and disposal of products that are still in active service life. For example, it is unclear why the widespread use and disposal of millions of computers and other electronics known to contain HBCD is not considered in the problem formulation. -Omission of conditions of use considered to be under the purview of other Federal Environmental Statutes that focus primarily on priority pollutants. TSCA was amended specifically because Congress found that these same existing environmental laws did not adequately protect the American people. -Omission of products knowingly or reasonably foreseen to incorporate HBCD and the complete omission of recycled products due to a perceived 'lack of intention' in fitting the Administrator's narrowly defined Conditions of Use. For example, the use and disposal of picture frames, food trays, coolers, and other products knowingly made with recycled EPS of high HBCD content is not considered. The decisions taken by EPA on these points were spurious and each are clearly inconsistent with the science and purpose of risk assessment and TSCA itself.
As currently practiced, the proposed conceptual models of the first ten problem formulations issued May 2018 do not meet the standard of relevance and representation for Tribal peoples, and therefore the model implementation process is essentially moot, and the applicability of the model to the 6.1 million people that Tribes represent is irrelevant.
We use the commonly accepted definitions of key terminology in risk assessment science. The following excerpts are drawn from the International Programme on Chemical Safety (IPCS) glossary (2004)3 and the Principles of Characterizing and Applying Human Exposure Models (2005)4 as published by the World Health Organization. Exposure assessment is "The process of estimating or measuring the magnitude, frequency, and duration of exposure to an agent, along with the number and characteristics of the population exposed. Ideally, it describes the sources, pathways, routes, and the uncertainties in the assessment" (IPCS, 2004). Exposure assessment is used in epidemiological studies to relate exposure concentrations to adverse health outcomes. Exposure assessment is also an integral component of risk assessment, the process that provides scientific information for risk management. Exposure assessment is based on exposure scenarios, which are defined as "A combination of facts, assumptions, and inferences that define a discrete situation where potential exposures may occur. These may include the source, the exposed population, the time frame of exposure, microenvironment(s), and activities. Scenarios are often created to aid exposure assessors in estimating exposure" (IPCS, 2004). An exposure model is a computational framework designed to reflect real-world human exposure scenarios and processes. A conceptual model is often illustrated by a block diagram, and it defines the physical, chemical and behavioural information and exposure algorithms by which the model mimics a realistic exposure scenario. ... The implementation of an exposure model should reflect the underlying conceptual model. Whenever the exposures of different subpopulations are expected to be different from each other, the exposure assessment probably needs to treat these subpopulations separately.

Y
Y
Y

75	NTTC	1	General, Exposure
76	NTTC	1	General, Exposure, PESS

N/A
N/A

Model evaluation can be seen as a three-step process: -1.The conceptual model must be validated. ...The (causal) relationships between the model input events and the output events must be real, and the nature, or shape, of these relationships must be known — at least approximately. -2.The model implementation must follow the conceptual model. The definitions of input and output variables must effectively describe the events of the conceptual model, and the algorithms and equations must sufficiently follow the true (causal) relationships of these events. -3. Assessing the applicability of the model to a set of specific problems is possibly the most difficult step. This includes evaluating how well the input values really describe the target system. Usually the input values have been measured and contain random or systematic measurement errors. The measured input data range is a combination of data uncertainty and true inherent variability, and in some new applications it is essential to be able to differentiate between the two (e.g. when one or the other dominates the distribution). Sometimes other models, questionnaire data or expert opinions are used in place of measurements to assign values to input variables Each of these inputs may or may not accurately describe the characteristics of the target system. Thus, even when the model is conceptually valid and carefully implemented, the model outputs may not agree with the system outputs.
In several of the following sections, the NTTC provides wide-ranging explanation of the vast extent of activities within tribal lifeways, aspects of "the system" (as referenced above) that needs to be modeled in the risk assessment process. In section 7 NTTC provides a graphic image of tribal lifeways, to provide a visual sense of the realm of all natural resources within tribal lifeways, and multitude of exposure scenarios and exposure pathways by which tribal populations are put at greater risk because their tribal lifeways have not been contained with TSCA risk assessment and risk evaluation processes. Also, in section 7, NTTC proposes the draft Possible Tribal Exposures Conceptual Model which received preliminary review and informal comment in an NTTC meeting with EPA OPPT earlier this year. Though in draft form, NTTC emphasizes that by using this conceptual model when evaluating unreasonable risk of injury to health (or their environment) to a potentially exposed and susceptible subpopulations, EPA will thereby protect both tribal populations and other subpopulations.

Y
Y

77	NTTC	1	General, Exposure, PESS
78	NTTC	1	General, Exposure, PESS
79	NTTC	1	General, PESS

N/A
N/A
N/A

In terms of subpopulations, consider how Barzyk (2010) discussed community-based risk assessment: "One of the primary differences between communities is in their patterns of exposure. ... Tools that isolate exposure routes and pathways for a given community and then incorporate toxicity information will lead to a better characterization of risk". This is key when considering potentially exposed and susceptible subpopulations, such as tribal groups whose patterns of exposure can be considered to be the "community" of an eco-region, e.g., the Pacific Northwest could encompass tribes and their lifeways from northern California, northerly along the Pacific coast into British Columbia, Canada and as far as the Prince William Sound in southcentral Alaska, U.S. -1. As currently practiced, the proposed conceptual models of the first ten problem formulations issued May 2018 do not meet the standard of relevance and representation for Tribal peoples, and therefore the model implementation process is essentially moot, and the applicability of the model to the 6.1 million people that Tribes represent is irrelevant. -2. Risk assessment of Tribal peoples for TSCA contaminants found in environmental media is relevant because Tribes are in contact with soil, sediment, and water as much or more than other population groups. -3. But the proposed problem formulations, and the risk assessments are not representative because they do not reflect nor model Tribal lifestyles. An entire population of people (6.1million strong) are not represented in any USEPA risk assessment work to date.
For millennia, tribal cultures were completely synonymous with and inseparable from the land and its resources. Tribes (used throughout this document) includes tribal people, resources, and other interests; interests (as sovereigns, seeking to govern/regulate tribal resources and as proprietors, i.e., holders of rights to land, water, fish, etc.) and the interests of individual Native people (whether they are tribal citizens or not; whether they live on a reservation or not); it is important to encompass tribal members who do not reside on tribal land, usual and accustomed areas, as well as treaty-protected resources; tribal lands as used in this report includes reservations, ceded lands, Usual and Accustomed areas (U&A) as well as communities inclusive of the Alaska Native Villages and Islanders and those without land bases. Continuing today, many tribes, tribal people and their clans are identified in their Native languages and in English translations as the name of singular or multiple seasonal locations or specific animals or insects, e.g. Water's Edge Clan (Navajo), People of the Herring Rock (Tlíngit), Where the Water Cuts Through (Po-wo-ge-oweenge), Red Willow Place (Tua-Tah), People of the standing of projecting rock or stone (Seneca), The Place where the locusts were taken out (Cayuga), The River with the two logs across it (Chickaloon).
Current Federal Indian Policy recognizes Tribal Sovereignty, Federal Trust Responsibility, and Government to Government Relationship, yet tribes today suffer health disparities, experience exposure pathways through tribal lifeways. Treaties are legally binding contracts between sovereign nations that establish those nations' political and property relations. Article VI of the U.S. Constitution holds that treaties "are the supreme law of the land." In return for taking vast Indian holdings and resources (i.e. land), the U.S. promised: Reservation Lands, Continued Sovereignty, Protection, Health Care, Education, Religious Freedom, Some Monies. Through the treaties they negotiated, tribes retained rights of self-government and jurisdiction. [exceprt from the 1855 Treaty with Yakama] Tribal sovereignty means that tribes are independent nations with the right to govern themselves by: Forming their own government, adjudicate legal cases within its boundaries, levy taxes within their borders, establish its membership, and retain government-to-government relationship with the U.S.

Y
Y
Y

80	NTTC	1	General, PESS

N/A

The Federal Government has a trust responsibility to protect tribal lands, assets, resources, and treaty rights, and uphold the promises made when treaties were made. With these recognized responsibilities and rights, Tribes have a unique legal status with the U.S. government. They are neither foreign nations, nor states. Tribes are distinct political communities defined in law as "domestic dependent nations." In the 1831 Cherokee Nation v. Georgia decision, the Supreme Court described the obligation of the U.S. to tribes as that of a guardian to his wards. Subsequent decisions have made it clear that the agencies of the federal government are to be held to the most stringent "fiduciary" (trust) standards. "Trust lands" describe lands held in trust by the U.S. for the benefit of a tribe or individual tribal member which cannot be alienated or confiscated through eminent domain. Additional case law since that 1831 Supreme Court decision confirms federal trust responsibility and protection tribal culture, identity, and ways of life. "Moral obligation of the highest responsibility and trust"-Seminole Tribs v. U.S. (1942). The United States is the trustee of Indian reserved rights, including fishing rights. -See, e.g., Joint Board of Control v. United States, 862 F.2d 195 (1988), 198 (9th Cir. 1988); Muckleshoot Indian Tribe v. Hall, 698 F. Supp. 1504, 1510-1511 (W.D. Wash. 1988). The obligation of the United States as trustee of Indian resources and rights extends to all agencies and departments of the Executive Branch. -See Pyramid Lake Paiute Tribe v. Department of the Navy, 898 F.2d 1410, 1420 (9th Cir. 1990), Covelo Indian Community v. FERC, 895 F.2d 581, 586 (9th Cir. 1990). The right to resort to the fishing places in controversy was a part of larger rights possessed by the Indians, upon the existence of which there was not a shadow of impediment, and which were not much less necessary to the existence of the Indians than the atmosphere they breathed.")U.S. v. Winans, 198 US 371 (1905). "...the Indians reiterated...that they wished to reserve the privilege of using the land for gathering, hunting, and fishing activities. They said that they could not live, deprived of these means of sustenance.Lac Court Oreilles Band of Chippewa Indians v. Leter P. Voigt, Seventh Circuit Court (1983).

Y

81	NTTC	1	General, PESS
82	NTTC	1	General, PESS, Exposure
83	NTTC	1	General, PESS, Exposure
84	NTTC	1	General, PESS, Exposure

N/A
N/A
N/A
N/A

Tribal nations, their governments, and their enrolled tribal members and tribal descendants are present in the United States and continue their ancestral tribal lifeways. There are 573 federally recognized tribes: 229 in Alaska, 110 in California and 234 in 33 other states. There are 61 state recognized tribes in 12 states. As of 2017, the U.S. Census Bureau's annual estimate of the Native American and Alaska Native population was 6.1 million which is 1.7% of the total U.S. population. Further, the Bureau projects that by 2050 the Native American and Alaska Native population will be 8.6 million, 2% of the total U.S. populations. The tribal nations with the largest populations include: Cherokee, Navajo, Choctaw, Chippewa, Sioux, Apache, Blackfeet, and Pueblo. The tribal lands—both trust lands and non-trust and non-reservation lands—accumulate to a collective geographical area today of 56 million acres which is equivalent to the size of Idaho state. Unfortunately, tribal people are afflicted by some of the least desirable statistics in the U.S.: the highest rates of suicide of any racial or ethnic group including white; highest rates of violence against women at more than double the rates of women of other races; overrepresentation in U.S. prisons and jails; historical and generational trauma from loss of people, lands and culture; posttraumatic stress disorder; more likely to have poorer overall physical and mental health and unmet medical and psychological needs; overrepresentation in the U.S. foster care system; and predisposition to heart disease, diabetes, and substance addiction. Many of these physical and mental health disparities are related to the historic and generational traumas, related to poverty induced by loss of people, lands, and language, related to the unmet obligations of the U.S. Government. These health disparities are exacerbated by environmental contaminants and pollutants in and around tribal resources. There is a legacy of toxic pollution on tribal lands and resources: "More than a century of hard rock mining has left a legacy of >160,000 abandoned mines in the Western USA that are home to the majority of Native American lands. ...Similar articles could be written focusing on impacts to tribal lands from coal strip mining, from the legacy of military bases, and from oil and gas development." Ineffective policies and the lack of infrastructure lead to environmental contamination through permitted exemptions to waste disposal allowing unlined landfills that accept household hazardous waste and unfiltered emissions from on-the-ground or other open burning. These exemptions also allow waste managers non-collection and non-treatment of landfill leachate. Additionally, tribal lands are commonly used for illegal waste dumping due to the significant void of law enforcement presence.
Despite attempts to disconnect tribes from traditional resources and tribal lifeways, tribal populations maintain a close relationship to the environment. The chemical exposures experienced by tribal people are not extremes of a general population range but consist of many discrete activities with legal protections. NTTC recognizes that prior to the Lautenberg Act, the burden of proof of toxicity was on the U.S.consumer. This is not adequate for the tribal community, especially considering the high-level consumption by tribal members of wild and natural resources as well as the U.S. government's trust responsibility and inability to provide safe water and sewer, and solid waste disposal on many Indian reservations and in many Alaska Native villages.
The below Graphic illustrates the unique exposures that Tribes face and that should be considered in any risk assessment procedure. The conceptual model that follows is intended for use in formulating the scope of any EPA chemical risk assessment. *See Conceptual Model Figures.* [Part 7, pages 10-11, presents a Conceptual Model of Tribal Exposures including a graphic reproduction and a flowchart]
NTTC supports EPA's comments on the September 30, 2015 technical call (U.S. EPA, 2015b) that EPA will evaluate additive exposures, such as oral exposures including fish consumption, drinking water consumption, potential for dust consumption and mouthing in the flame retardant risk assessments. However, in such an evaluation of oral exposures, EPA must include the high-end exposure approach with fish consumption rates of subsistence fishers.

Y
Y
Y
Y

85	NTTC	1	General, PESS, Exposure
86	NTTC	1	General, PESS

N/A
N/A

Mitigation by Avoidance or Replacement is Not an Option. When at least half of your diet is derived locally, you cannot stop eating that and switch to other foods. This type of mitigation action used in past risk management strategies, i.e., "don't consume more than X amount in Y timeframe," amounts to an unfunded mandate and forced cultural loss which is documented to lead to a range of societal ills that cause economic impact as well. As Ocampo wrote: Many First Nations [Indigenous People] peoples embrace a shared group identity whose substance is formed not just by one's relationship to the community but also to the land and one's ancestors, which may include plants, animals and other elements of nature. For example, traditional Native Hawai'ians consider the taro, a root staple that nurtures them, a physical ancestor now under their guardianship. Thus, reduction or dispossession of land/loss of stewardship of one's traditional plants and animals is experienced as an alienation or unmooring from the self, and in some communities is directly correlated with suicide (i.e., among the Guarani of Argentina - see Robinson, 2008).
Whitbeck, Walls, Johnson, Morrisseau, & McDougall (2009) studied depression and historical loss among Indigenous adolescents, reporting that the measures of perceived historical loss and depression were separate but related constructs. Even when controlling for effecting influences such as family factors, discriminatory treatment, and proximal negative life events, an adolescent's perceived historical loss had independent effects on their depressive symptoms. The construct of historical loss is discussed in terms of Indigenous ethnic cleansing: military defeat, relocation to approximate penal colonies, starvation, neglect, forbidden to practice traditional means of survival and spiritual traditions, forced assimilation, children kidnapped and reeducated in settings that ignored kinship patterns, traditional language use punished, and efforts to replace traditional religious beliefs with Christianity, no specific end to government policies of assimilation, and no acknowledgement of ethnic cleansing or apology for it from the U.S. government. Reinschmidt, Attakai, Kahn, Whitewater, & Teufel-Shone (2016) developed the Stories of Resilience Model from interviewing and documenting Urban American Indian Elders' experiences of historical trauma and resilience. "For Indigenous people removed as children to boarding/residential schools or adopted by White families off reservation, this meant being removed from the tribal lands that were closely tied in with culture and traditions, including subsistence practices (farming and hunting), beliefs (traditional spirituality), and values (having respect for oneself and others). Separation from their families led to a loss of contact with relatives, especially elders, who passed on culture and traditions. Family members could no longer teach Native languages or engage children in family activities."

Y
Y

87	NTTC	1	General, PESS
88	NTTC	1	General, PESS

N/A
N/A

Despite these historic and generational traumas, tribes have maintained cultural practices and values, and many tribes—but not all—maintained their Indigenous languages, stories, songs, and millennia of history. Thus, contrary to the efforts of colonization, assimilation, and attempts of genocide, research of Indigenous survivors is demonstrating that traditional spirituality, traditional practices, and cultural identity are proven protective factors for Indigenous children and adults. Further, there is accumulating evidence that traditional spirituality and practices are associated with alcohol cessation, are negatively related to depressive symptoms and suicidal behaviors among adults, and that they are associated with academic success, self-esteem, and prosocial behaviors among adolescents. Reinschmidt et al reference work by Kirmayer, Dandeneau, Marshall, Phillips, & Williamson (2011, 2012) supporting that community resilience is compatible with Indigenous values of relationships among people and with the environment. Distinct notions of personhood, where individuals are connected to the land and the environment, shape Indigenous ideas of individual resilience. “Land plays a critical sacrosanct role: it is itself sacred, with tribal-specific meaning, and it is also often directly connected to ritual sacred sites, where ceremonies and obligations are expected to be fulfilled.” (Walters, Simoni & Evans-Campbell, 2002.)
Resilience strategies in the context of the community included being “connected to the community,” “involved in local community cultural activities,” and “knowing one’s Native language” were. Another elder’s story demonstrated the connection between personal, family, and community resilience: "think the values that I picked up when I was growing up was making my baskets. That was one of the things that REALLY was good for me... I was taught by my mother and I learned that it really did help me. She ...showed me how to prepare to make basket: first to go out and get the plants... I have to talk to the plants. You go up to the plants while you get them, so that it will help you, strengthen you, give you the courage to go on with your life and it’s really not just making baskets. It’s something that, it’s sort of like a sacred secret. So that’s what I did. I found out that that’s REALLY helped me a lot. Not just making baskets, but keeping up with our tradition, something that our people used to make and use for many things. And also, I sell my baskets a lot so that helped me in many ways...that was my income when I couldn’t work..." The Indigenous notion of personhood connects individuals to larger contexts, including family, community, spirituality and history. As described by the elders in the study, and in the literature (Kirmayer et al., 2009, 2012), the Indigenous notion of the self (or person or individual) is one of connectedness. Individual resilience thus must be understood as systemic in nature, because it refers to Indigenous notions of the individual that are characterized by connectedness. In telling their stories, elders talked about people who served as role models for them, about being role models themselves, and about the importance of role models. Most elders fondly remembered their grandparents, parents, or aunts. These relatives imparted knowledge and skills, including gardening, butchering, counseling others, being medicine men, and knowing traditions around birth and death.

Y
Y

89	NTTC	1	General, PESS
90	NTTC	1	General, Exposure
91	NTTC	1	General, Exposure

N/A
N/A
N/A

Healing among North American indigenous populations have common themes, shared health beliefs and a unified perspective of bio-psycho-socio-spiritual approaches and traditions, regardless of tribal-specific differences in healing practices, like feathers of different birds, sweat lodge or bonya steam bath, burning a dried herb or burning a fire dish of food. "The culture is the primary vehicle for delivering healing." Bassett, Tsosie, & Nannauck. 2012) "Native diets, ceremonies that greet the seasons and the harvests, and the use of native plants for healing purposes have been used to live to promote health by living in harmony with the earth." Koithan & Farrell (2010). Food from the land gives people life and brings them wellness. (Youth Taking Action, no date (n.d.)) "Alaska Natives have been nourished by foods from the land, air, and water for thousands of years (Alstrom & Johnson, n.d.)34. They have had a lifelong association with these foods, seeking them, harvesting them, cleaning them, preparing them to be eaten or stored, keeping the foods safe from loss of spoilage, and enjoying them as foods. People take great comfort from eating the foods they've grown up with. These foods can be very comfortable to eat in times of illness and healing, and are very rich in the nutrients necessary for good health. Native foods tend to be very good sources of nutrients like protein, iron, Vitamins A, D and E, and low in saturated fats and sugars. Native foods are the heart of culture and health. They provide close ties to the land and the seasons and the environment. Participating in harvesting, preparing, sharing and eating the foods along with others contributes to spiritual well being."
Disposal pathway regardless must be considered because contamination of media occurs even with best practice and facilities.
Throughout Asia, non-PBDE BFRs like HBCD, have extensively polluted coastal waters (Isobe, Ogawa, Ramu, Sudaryanto, & Tanabe 2012). They used mussels as a bioindicator, as did studies by the US National Oceanic & Atmospheric Administration of coastal US waters (Isobe et al., 2012), Isobe et al were studying the presence of BFRs, the range throughout Asia, and the levels of concentrations. Among the three HBCD diastereoisomers, α-HBCD was the dominant isomer followed by γ- and β-HBCDs. Concentrations of HBCDs and DBDPE in mussels from Japan and Korea were higher compared to those from the other Asian countries, indicating extensive usage of these non-PBDE BFRs in Japan and Korea. Higher levels of HBCDs and DBDPE than PBDEs were detected in some mussel samples from Japan. The results suggest that environmental pollution by non-PBDE BFRs, especially HBCDs in Japan, is ubiquitous. This study provides baseline information on the contamination status of these non-PBDE BFRs in the coastal waters of Asia. More than 1,500 construction and demolition debris (CDD) landfills operate in the United States (U.S.), and U.S. federal regulations do not require containment features such as low-permeability liners and leachate collection systems for these facilities (Powell, Jain, Smith, Townsend, & Tolaymatl; 2015). Here we evaluate groundwater quality from samples collected in groundwater monitoring networks at 91 unlined, permitted CDD landfills in Florida, U.S. A total of 460,504 groundwater sample results were analyzed, with a median of 10 years of quarterly or semiannual monitoring data per site including more than 400 different chemical constituents. Downgradient concentrations of total dissolved solids, sulfate, chloride, iron, ammonia-nitrogen, and aluminum were greater than upgradient concentrations ($p < 0.05$). At downgradient wells where sulfate concentrations were greater than 150 mg/L (approximately 10% of the maximum dissolved sulfate concentration in water, which suggests the presence of leachate from the landfill), iron and arsenic were detected in 91% and 43% of samples, with median concentrations of 1,900 µg/L and 11 µg/L, respectively. These results show that although health-based standards can be exceeded at unlined CDD landfills, the magnitude of detected chemical concentrations is generally small and reflective of leached minerals from components (wood, concrete, and gypsum drywall) that comprise the bulk of discarded CDD by mass.

Y
Y
Y

92	NTTC	1	General
93	NTTC	1	General, Exposure
94	NTTC	1	General, PESS, Exposure
95	NTTC	1	General, PESS, Human Health

N/A
N/A
N/A
N/A

In August 2015, EPA published for public comment its TSCA Work Plan Chemical problem formulation and initial assessment documents for the three flame retardant clusters Brominated Bisphenol A (TBBPA), Chlorinated Phosphate Esters (CPE), and Cyclic Aliphatic Bromides (HBCD) (USEPA 2015c). In response NTTC provided written comments to that docket which we recapture here in relevance to problem formulation and risk evaluation under the amended TSCA.
NTTC appreciates EPA's inclusion of fish consumption by subsistence fishers and their children when evaluating exposure pathways for CPE. We specifically highlight EPA's commitment to account for the high-end fish consumption of subsistence fishers—including pregnant women, children and adults—the majority of whom are the tribal population.
With Tribes as a representative population for greater environmental media exposure risk, any resultant action levels will not only protect tribes and the general population, but the ethnic, minority, and rural population groups that may be at higher risk due to their customary lifestyle and activities and/or traditional practices. Fishing illustrates this point. Fishing is a universal practice for Alaska Tribes, potential exposure via ingestion of contaminated fish is higher due to higher consumption, as is potential exposure via inhalation through smoking fish, and other heat preparation methods particularly with poor indoor ventilation, via potential absorption when fishing and preparing a greater amount of fish, via non-dilution of contaminated fish with fish from another location due to unavailability of store-bought fish, via particular practices associated with fishing, which may include gathering greens and using untreated water near the fishing spot, etc. Also, the full Tribal population – from infant to elder, disabled, single parents with small children and relative living outside the village – is exposed due to sharing of fish. This is a magnified representation of the Alaska population as a whole, particularly the rural population, which tend to fish for, and share and eat fish like salmon, at a much greater rate than their counterparts in the contiguous states. The same can be said for exposure to contaminated "game meats", marine mammals, berries, water and other environment sources due to customary food resources and recreational activities. With Tribes as representative, the full Alaska population is protected.
The sociocultural consequences to Tribal communities of overexposure to chemicals are as significant, or more significant, compared to the consequences to other groups. The small population size, high-context, and group-oriented nature of Tribal populations translates to substantial impact on health and well-being when a Tribal member is negatively affected by chemical exposures. For example elders are a significant resource in their community and fill multiple roles. Teachers of cultural values and mores for their community including other older adults that are younger than the elder in addition to children and teens. It is well documented that tribal people's socio-cultural knowledge base is more internalized and is not adequately learned via verbal or written instructions. It must be acquired over a lifetime of experiencing the day-to-day contexts of being a tribal person and relating with elders that have fully acquired the knowledge in their time by being with generations past. Sources of historical information shared with their community including other older adults that are younger than the elder in addition to children and teens. Leaders whose experience provides stability and experience to the tribal council and in consultations with government agencies. Caretakers for extended family members, providing unpaid childcare. A grandmother who develops cancer will not be able to care for her grandchildren, parents may miss work resulting in job or income loss, or children may miss a critical mentor role or be injured because they are left alone.

Y
Y
Y
Y

96	NTTC	1	General, PESS, Human Health
97	NTTC	1	General, PESS, Exposure
98	NTTC	1	General, PESS, Exposure
99	NTTC	1	General, PESS, Exposure

N/A
N/A
N/A
N/A

Impacts to societal health and well-being contribute to disproportionate health and socioeconomic indicators. E.g., exposure to a certain chemical affects childhood brain development, causing neuro-developmental delays, which are compounded as the child progresses through school and Tribal populations suffer from low high school and college graduation rates.
While NTTC recognizes that part of EPA's risk assessment process is collecting existing data on the chemicals in question, asking tribes to fill this data gap is unreasonable. EPA must provide funding before starting the process (at least more than one year prior) to request tribes gather information. Specifically, sampling within tribal homes in high-risk areas would provide valuable data to further complete risk assessments accounting for high-risk, vulnerable tribal populations. EPA must take into account widespread backyard open burning and open burning at both municipal and construction & demolition landfills. Tribal and other rural citizens are exposed to chemicals in commerce via this pathway, including HBCD. These types of burning are prevalent in underserved tribal communities on reservations in the U.S. and other rural lands, including nearly every community in the State of Alaska. These communities rarely have proper burn units nor appropriate safety protocols to prevent residents' inhalation.
Again, regarding fish consumption and the rate referenced above, in relation to population scenarios, the tribal population scenario is the most appropriate to use for risk assessments by EPA, because their rules indicate that they are to protect the population of highest risk. As identified in the 2015 problem formulation for the HBCD cluster, EPA must use fish consumption rates for subsistence fishers in aggregate exposure for those who rely heavily on locally sourced fish.
It is imperative that EPA consider potential cumulative exposure—including multiple chemical exposure—in these risk assessments because it is an on-going void in implementing environmental justice policies. This is a significant problem that EPA is not considering cumulative exposure in the risk assessment process at this time. It is an environmental justice issue affecting tribes, who rely heavily on high volumes of fish and aquatic mammals for half or more of their diet. Additionally, a large percentage of American Indian and Alaska Native communities are at or below the poverty level. This translates to lower replacement cycles of furniture, toys, clothing etc. from those with higher toxicities to more recently manufactured items of lower toxicities. For example, although PCB is no longer manufactured, studies have detected it in Puget Sound tissue sample monitoring. EPA must also look at wastewater outside of only the Toxics Release Inventory, which does not account for small local government facilities like unlined but permitted landfills, unpermitted landfills, open dumps, and open dump and backyard burning. As the Council has previously discussed with EPA, the stovepiped processes of EPA fails in protecting tribes from exposures to chemical in commerce.

Y
Y
Y
Y

100	EPN_CommentJuly312018	1	RegNex
101	EPN_CommentJuly312018	1	Exposure, PESS
102	EPN_CommentJuly312018	1	Exposure, RegNex, Policy

N/A
N/A
N/A

The Environmental Protection Network (EPN) is providing the following comments on the problem formulations for asbestos, HBCD and carbon tetrachloride, which we find are setting improper precedents for future chemical risk evaluations under the new Chemical Safety Act amendment to TSCA. The final rule states that EPA is given discretion to determine the conditions of use that it will address in its evaluation of a priority chemical, "in order to ensure the agency's focus is on the conditions of use that raise the greatest potential for risk." The final rule mentions excluding de minimis conditions of use or conditions of use that have been adequately addressed by another regulatory agency. The final rule also states that while the statute is ambiguous as to whether the conditions of use should include legacy uses, "in a particular risk evaluation, EPA may consider background exposures from legacy use, associated disposal and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses."
In contrast to this final rule, the Chemical Safety Act is clear that EPA must identify and evaluate risks resulting from all intended or reasonably foreseen, as well as known conditions of use of a chemical substance. EPA is required to make a determination on the chemical substance as to whether it presents an unreasonable risk of injury to health or the environment without consideration of costs or other non-risk factors due to a single use or any combination of uses. If an unreasonable risk is found, TSCA provides EPA with a broad set of authorities to deploy actions that fully eliminate the unreasonable risk. The timing, frequency, location and duration of all exposures and their magnitude at a given point in time and space are key to determining unreasonable risk for susceptible subpopulations such as infants, pregnant women, the elderly, workers and disproportionately exposed communities. TSCA requires two kinds of risk assessment, one for a single or sentinel exposure to evaluate acute toxic effects and one for aggregate exposure of co-occurring sources to evaluate chronic toxic effects. Since all 10 chemicals addressed in these first problem formulations have chronic toxic effects, a comprehensive aggregate assessment of all co-occurring exposures is critical since excluding even one pathway will underestimate cancer and non-cancer effects.
In the following sections of our public comments, the Environmental Protection Network will explain: 1) why the asbestos and HBCD problem formulations should not exclude pathways of exposure to legacy uses; 2) why the asbestos problem formulation should not exclude pathways of exposure regulated under other programs; 3) why the carbon tetrachloride problem formulation should either evaluate the conditions of use now designated as "de minimis" or provide a science-based justification for their exclusion and rationale for not seeking additional information from industry; and 4) why EPA needs to take the lead in addressing workplace risks while consulting with OSHA.

Y
Y
Y

103	EPN_CommentJuly312018	1	RegNex
104	EPN_CommentJuly312018	1	RegNex

N/A
N/A

2. EPA's Proposed Approach to Risk Evaluation of Exposures Associated with Other EPA Regulatory Programs is Contrary to Plain Statutory Language and is Legally Unsound; is Scientifically and Methodologically Unsound and is Not Efficient. In each of the draft problem formulation documents for the first ten existing chemicals, EPA includes the following paragraphs (see, for example, page 13 of the 1-Bromopropane Problem Formulation): ". . . EPA also identified certain exposure pathways that are under the jurisdiction of regulatory programs and associated analytical processes carried out under other EPA-administered environmental statutes – namely, the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA), and the Resource Conservation and Recovery Act (RCRA) – and which EPA does not expect to include in the risk evaluation. As a general matter, EPA believes that certain programs under other Federal environmental laws adequately assess and effectively manage the risks for the covered exposure pathways. To use Agency resources efficiently under the TSCA program, to avoid duplicating efforts taken pursuant to other Agency programs, to maximize scientific and analytical efforts, and to meet the three-year statutory deadline, EPA is planning to exercise its discretion under TSCA 6(b)(4)(D) to focus its analytical efforts on exposures that are likely to present the greatest concern and consequently merit a risk evaluation under TSCA, by excluding, on a case-by-case basis, certain exposure pathways that fall under the jurisdiction of other EPA-administered statutes. EPA does not expect to include any such excluded pathways as further explained below in the risk evaluation. The provisions of various EPA-administered environmental statutes and their implementing regulations represent the judgment of Congress and the Administrator, respectively, as to the degree of health and environmental risk reduction that is sufficient under the various environmental statutes." Although these paragraphs are contained in all ten of the problem formulation documents, EPA offers no further definition of what it means by "under the jurisdiction" of regulatory programs or, "associated analytical processes . . .under other EPA administered statutes."
We have focused our comments on this issue in the asbestos problem formulation as an example case. All of our objections and concerns about this approach for asbestos would apply to the other nine chemicals, and depending on specifics, the use of this approach for those chemicals would likely raise additional concerns as well.

Y
Y

105	EPN_CommentJuly312018	1	RegNex, Exposure

N/A

Comments on Exclusion of Consideration of Exposures Associated with Other EPA Regulatory Programs, with specific reference to the asbestos problem formulation:

a. EPA's planned approach to exclude exposure pathways associated with other EPA statutes is contrary to plain statutory language and legally unsound.

EPA cites only TSCA Sec (6)(b)(4)(D) as a basis for the decision to omit significant exposure pathways. The brief language of that provision, providing for publication of the key elements of a proposed risk assessment, offers no basis to alter the administrator's obligation under Section 6. Indeed, the treatment of risks that may also be subject to other EPA-administered statutes is expressly addressed in TSCA Sec 8(b), which provides:

"(1) The Administrator shall coordinate actions taken under this chapter with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this chapter. This subsection shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws.

(2) In making a determination under paragraph (1) that it is in the public interest for the Administrator to take an action under this subchapter with respect to a chemical substance or mixture rather than under another law administered in whole or in part by the Administrator, the Administrator shall consider, based on information reasonably available to the Administrator, all relevant aspects of the risk described in paragraph (1) and a comparison of the estimated costs and efficiencies of the action to be taken under this subchapter and an action to be taken under such other law to protect against such risk."

Y

106	EPN_CommentJuly312018	1	RegNex, Exposure
107	EPN_CommentJuly312018	1	RegNex

N/A
N/A

Comments on Exclusion of Consideration of Exposures Associated with Other EPA Regulatory Programs, with specific reference to the asbestos problem formulation: a. EPA's planned approach to exclude exposure pathways associated with other EPA statutes is contrary to plain statutory language and legally unsound. EPA cites only TSCA Sec (6)(b)(4)(D) as a basis for the decision to omit significant exposure pathways. The brief language of that provision, providing for publication of the key elements of a proposed risk assessment, offers no basis to alter the administrator's obligation under Section 6. Indeed, the treatment of risks that may also be subject to other EPA-administered statutes is expressly addressed in TSCA Sec 8(b), which provides: "(1) The Administrator shall coordinate actions taken under this chapter with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this chapter. This subsection shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws. (2) In making a determination under paragraph (1) that it is in the public interest for the Administrator to take an action under this subchapter with respect to a chemical substance or mixture rather than under another law administered in whole or in part by the Administrator, the Administrator shall consider, based on information reasonably available to the Administrator, all relevant aspects of the risk described in paragraph (1) and a comparison of the estimated costs and efficiencies of the action to be taken under this subchapter and an action to be taken under such other law to protect against such risk."
Further, the specific language of Section 6 provides, in (F) that the administrator is to "integrate and assess available information on hazards and exposures," obviously inclusive of information developed under other EPA statutes. These provisions clearly establish the role for other EPA programs: information known through other statutory programs shall be considered in the risk evaluation phase for existing chemicals under TSCA, and after completion of the risk evaluation, the administrator must follow a process to consider the potential use of other programs to address the risk under the TSCA standard. The proposed EPA approach would reverse and fundamentally alter this process.

Y
Y

108	EPN_CommentJuly312018	1	Exposure, RegNex, PESS
109	EPN_CommentJuly312018	1	Exposure, Policy
110	EPN_CommentJuly312018	1	RegNex
111	EPN_CommentJuly312018	1	RegNex, Policy

N/A
N/A
N/A
N/A

Further, the omission of important exposure pathways makes it impossible to make the finding required under Sec 6(b)(4)(A) which requires the administrator conduct risk evaluations "to determine whether a chemical substance presents an unreasonable risk...to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation." "Environment" is defined to include "air, water and land" and the relationship among and between these elements and with "all living things." The statute defines "conditions of use" to mean the circumstances under which the substance is "manufactured, processed, distributed in commerce, used or disposed." A risk assessment that omits exposures considered under other statutes cannot be assumed to meet this standard. Indeed, other statutory schemes generally do not operate under comparable environmental standards and requirements for consideration. They often require consideration of costs, technical feasibility or other non-risk factors. They are not designed to consider the interaction among air, land and water, but are focused instead on exposure in the specified medium. Consideration of special subpopulations is rarely required and may not even be considered under other statutory schemes. In addition, even when these other regulatory programs are implemented perfectly, they only reduce exposures down to the regulatory standard, they do not eliminate exposures.
TSCA requires specific inclusion of disposal in evaluation of the subject conditions of use; omission of disposal exposures from substances subject to RCRA may have the effect of omitting disposal entirely from the required statutory scope of consideration for the subject conditions of use.
All of these inadequacies make it impossible for the administrator to rely on the work of other regulatory programs to meet the requirements for Section 6 risk evaluations. Indeed, the agency has made no attempt to show any comparability or even consistency between the TSCA risk assessment requirements and the approaches of the regulatory programs associated with these omissions.
EPA offers no analysis of the way in which evaluations under other statutes have met the procedural requirements of TSCA.

Y
Y
Y
Y

112	EPN_CommentJuly312018	1	RegNex, Policy
113	EPN_CommentJuly312018	1	RegNex, Policy
114	EPN_CommentJuly312018	1	RegNex, Exposure

N/A
N/A
N/A

b. EPA's planned approach to exclude important exposures associated with other EPA-statutes is also scientifically and methodologically unsound. Risk assessments that are currently available (for appropriate consideration under TSCA Sec 6(F)) are identified in the problem formulation document. Notably, the identified risk assessments under the SDWA and the CAA are from 1985 and 1986 respectively. Nothing under RCRA is identified. Obviously, these programs have not completed risk assessments reflecting changes in the science for more than 30 years. Conclusions based on any such assessments would, at a minimum, require a serious updating of most aspects of the science involved. There is no indication that EPA intends to devote the resources that would be required to update program-specific risk assessments for asbestos even for the narrow purposes of determining whether further action is warranted under such statute. EPA's other regulatory programs have limited resources and many competing priorities, including those required by specific statutory provisions and/or court orders. Congress has provided additional resources specifically for implementation of TSCA, which can compensate for the lack of resources in these other programs. In addition to the advantage TSCA affords EPA to conduct risk assessments and issue regulations covering all sources of exposure, EPA should use the potent information gathering provisions of TSCA 8(a) and 8(d) to update or supplement the risk evaluations conducted under other statutes which are so out of date today. Staff from other program offices should be involved in the assessments conducted under TSCA so they can assist the TSCA program while also updating their media-specific risk evaluations.
c. EPA's planned approach to justify the exclusion of pathways regulated by other programs based on efficiency is flawed. EPA invokes efficiency as a rationale for its approach to excluding exposures under other statutes. But it is clear that nothing is preventing the agency from making use of prior work conducted under other statutes and the expertise developed throughout the agency. Further, as noted above, TSCA provides a clear path by which the administrator may, after conducting the risk assessment and making the risk findings required by TSCA, turn to all the other statutes he administers as part of crafting a risk management approach for existing chemicals under TSCA. This extreme, legally and scientifically unsound refusal to consider significant exposures clearly resulting from current conditions of use is not warranted on efficiency grounds.
4. EPA's Potential Approach to Rely on OSHA to Regulate Worker Exposure is Flawed. In addition to the inadequacy of EPA's proposed exclusion of exposures that are "already regulated" by EPA (by statutes other than TSCA, such as the CAA), as discussed above in these comments, this exclusion also reveals a potentially very serious flaw in EPA's methods if the agency intends to apply the same approach to workplace exposures. The Chemical Safety Act requires EPA to consult with OSHA "prior to adopting any prohibition or other restriction relating to a chemical substance with respect to which the Administrator has made a determination to address workplace exposures." So far, the agency has been silent regarding how it intends to address workplace risks, but the strategy of having EPA "punt" its responsibilities regarding workers by transferring them to OSHA is being heavily advocated by industry groups, and it must not remain unchallenged. Any wholesale "referral" to OSHA for potential regulation would in effect leave the workers unprotected, because it is well known that OSHA is unable to promulgate occupational health standards in a timely fashion, if at all.

Y
Y
Y

115	EPN_CommentJuly312018	1	RegNex, Exposure
116	EPN_CommentJuly312018	1	RegNex, Exposure
117	Healey_CommentAugust72018	1	General

N/A
N/A
N/A

To better understand this concern, it is important to note that all ten chemicals slated for analysis at this stage of the TSCA mandates, and eventually slated for potential regulation, have their highest exposures and pose their most serious risks to workers who manufacture, process, transport, dispose of or otherwise handle these chemicals. This is no surprise: workers are nearly always the first and most seriously exposed populations, experiencing the highest risks. In addition, four of the chemicals [1-BP, HBCD, NMP, and PV25] are not regulated at all by OSHA, and the remaining six are currently regulated by OSHA standards that are scientifically obsolete, based on studies more than a half century old. Because of OSHA's inability to regulate in a timely manner, referral of the responsibility to regulate these chemicals would condemn workers to significant risks for a long time, or even indefinitely.Table 1 shows the contrast between current OSHA standards for the ten chemicals with more modern standards (Cal-OSHA) or recommendations (NIOSH and ACGIH). It is evident that current OSHA protections are highly inadequate and TSCA regulation will be necessary. [Table 1 illustrates differences between OSHA PELs, Cal-OSHA PELs, NIOSH RELs, and ACGIH TLVs. The values for asbestos were the same across all standards/guidelines, and the values for OSHA and CAL-OSHA were the same for methylene chloride (25 ppm). Values for the other standards/guidelines were less than OSHA for all other chemicals.]

While it is commendable that the agency recognizes the workplace hazards posed by these chemicals and intends to evaluate the risks at this stage, it is crucial that EPA state explicitly that it will take steps to make sure that workplace risks are regulated in a timely fashion under TSCA, even as OSHA, NIOSH and other agencies are consulted in the process of doing so, as TSCA allows.

The Attorneys General of Massachusetts, California, Hawaii, Maine, Maryland, New Jersey, New York, Oregon, Vermont, Washington, and the District of Columbia appreciate this opportunity to comment on the U.S. Environmental Protection Agency's ("EPA") problem formulations of the risk evaluations for the ten chemical substances (the "Initial Ten TSCA Chemicals") that are the subject of EPA's initial chemical risk evaluations required under the Frank R. Lautenberg Chemical Safety for the 21st Century Act (the "Lautenberg Act"), amending the Toxic Substances Control Act (TSCA). In its notice dated June 11, 2018, EPA requested comments on the problem formulation documents for the Initial Ten TSCA Chemicals (the "Problem Formulations") to assist the agency in developing its draft risk evaluations for these chemical substances. The Attorneys General submit the following comments for EPA's consideration as EPA proceeds with its risk evaluations of the Initial Ten TSCA Chemicals.

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Y

118	Healey_CommentAugust72018	1	General
119	Healey_CommentAugust72018	1	General

N/A
N/A

The undersigned Attorneys General support the goal that motivated the Lautenberg Act amendments to TSCA, signed into law on June 22, 2016: the goal of reforming TSCA to remove obstacles that had prevented EPA from playing a more robust role in protecting public health and the environment from toxic chemicals. Unfortunately, the Problem Formulations are antithetical to that purpose. EPA takes the position that TSCA authorizes the agency to consider in its risk evaluation a mere subset of the uses for which the chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed. That interpretation would result in EPA's risk evaluations being woefully incomplete by ignoring significant exposure pathways for the chemical substances. This unlawfully restrictive application of TSCA ignores that Congress intended for EPA to assess a chemical in its entirety, based on all identifiable conditions of use, including ongoing and legacy uses, like the ubiquitous continued use of notoriously hazardous asbestos, in its risk evaluations. For this reason, the Problem Formulations would produce deeply flawed risk evaluations that would make it impossible for EPA to fulfill its statutory mandate under Section 6 of TSCA of establishing requirements for the Initial Ten TSCA Chemicals to ensure that none of the chemical substances presents "an unreasonable risk of injury to health or the environment." We thus urge EPA to issue revised Scopes of the Risk Evaluation, which the Problem Formulations are meant to refine, for each of the Initial Ten TSCA Chemicals to address the agency's fatally flawed approach to identifying the conditions of use as that term is understood under TSCA and to ensure that the data EPA considers in the process satisfies TSCA's "best available science" standards. Given the well-documented hazards of many of the Initial Ten TSCA Chemicals, we fully expect that after conducting appropriate risk evaluations, EPA will impose new protective restrictions, and in some cases bans, for the chemical substances in this group.
These comments proceed as follows. In Part I, we describe TSCA's requirements for the risk evaluations. In Part II, we provide a summary of our states' interests with regard to the risk evaluations. In Part III, we offer analysis supporting our call for EPA to reconsider its approach to its conditions of use characterizations and to ensure that data consistent with TSCA's requirements are considered in the risk evaluation process. Finally, we suggest an appropriate risk evaluation path forward that will satisfy Congress's mandate under TSCA that EPA act to eliminate unreasonable risks of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to potentially exposed or susceptible subpopulations.

Y
Y

120	Healey_CommentAugust72018	1	General/Exposure
121	Healey_CommentAugust72018	1	General

N/A
N/A

Under TSCA, as amended, EPA is required to prioritize chemical substances for regulatory review and then assess the risks posed by the chemicals identified as priorities. Risk is a function of hazard and exposure, and to evaluate the risks posed by a chemical as TSCA requires it is necessary to consider the full range of exposures. However, in the Problem Formulations EPA has, without basis in law or fact, eliminated from its risk evaluation process many significant sources of chronic exposure to these toxic chemical substances. Section 6 of TSCA requires EPA systematically to prioritize for risk evaluation, and to evaluate the potential risks presented by, the manufacture, processing, distribution in commerce, use, or disposal of chemical substances or mixtures. Within 180 days of enactment of the 2016 TSCA amendments, that is by December 19, 2016, EPA was required to begin risk evaluations on ten chemical substances drawn from the agency's TSCA Work Plan for Chemical Assessments: 2014 Update (the "2014 TSCA Work Plan Update") and to publish the list of such chemical substances during the 180-day period. On December 19, 2016, EPA designated the Initial Ten TSCA Chemicals for risk evaluation: Asbestos, 1-Bromopropane, 1,4-Dioxane, Carbon Tetrachloride, Cyclic Aliphatic Bromide Cluster (also known as HBCD), Methylene Chloride, N-Methylpyrrolidone (NMP), Pigment Violet 29, Tetrachloroethylene (also known as Perchloroethylene), and Trichloroethylene (TCE).
Under TSCA, Section 6(b)(4)(A), EPA is required to conduct a risk evaluation for each of the Initial Ten TSCA Chemicals, and for chemicals later designated as "high-priority," to determine whether the ". . . chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of cost or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." And under TSCA, Section 6(b)(4)(D), EPA was required to publish the scope of the risk evaluation to be conducted for each of the Initial Ten TSCA Chemicals within six months after the initiation of the risk evaluation. On July 7, 2017, EPA published its Notice of Availability for the Scopes of the Risk Evaluations To Be Conducted for the First Ten Chemical Substances Under the Toxic Substances Control Act. Under TSCA, those scopes must include the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider in his or her analysis. Thereafter, EPA published the subject Problem Formulations in the Federal Register on June 11, 2018,16 with the Problem Formulations being said to function to refine the earlier-published scope documents.

Y
Y

122	Healey_CommentAugust72018	1	General
123	Healey_CommentAugust72018	1	General
124	Healey_CommentAugust72018	1	Other, Policy

N/A
N/A
N/A

Our states have a significant interest in ensuring that the risk evaluations for the Initial Ten TSCA Chemicals are conducted in accordance with TSCA. The Initial Ten TSCA Chemicals were drawn from the agency's 2014 TSCA Work Plan Update, as required by TSCA, and were selected based on their hazard and potential exposure, as well as other factors such as persistence and bioaccumulation. For example, asbestos is a known carcinogen, with acute and chronic toxicity associated with inhalation exposures; tetrachloroethylene (also known as perchloroethylene or perc) is a probable human carcinogen with high reported releases to the environment; and n-methylpyrrolidone (NMP) has high reported releases to the environment and is associated with reproductive toxicity. The potential for substantial harm to public health and the environment associated with the Initial Ten TSCA Chemicals resulted in their being chosen as the first candidates for risk evaluation. Thus, the consequences for our states' residents of a federal failure to identify those risks and to regulate accordingly may be dire, with the potential for even greater risk to susceptible subpopulations, where the failure to perform a full analysis may have the most severe adverse impact. As evidenced by the following overview of actions by many of the participating states and the District of Columbia, the unreasonable risks to human health and the environment that the Initial Ten TSCA Chemicals pose justifies governmental response. In fact, it is just such health- and environment-protective regulation at the federal level that informed the 2016 amendments to TSCA. Additionally, the data listed below that demonstrates the prevalence of the Initial Ten TSCA Chemicals in our states further confirms the states' significant interest in ensuring that EPA implements TSCA as it was revised by the Lautenberg Act: to eliminate "unreasonable risk of injury to health or the environment" from the "intended, known, or reasonably foreseen" manufacturing, processing, distribution in commerce, use, or disposal of chemicals.
Massachusetts: Under the Massachusetts Toxics Use Reduction Act, G.L. c. 21I ("TURA"), large-quantity chemical users in the Commonwealth are required to report annually on their use of toxic chemicals and conduct toxics use reduction planning every two years. Each of the Initial Ten TSCA Chemicals, with the exception of Cyclic Aliphatic Bromide Cluster, also known as HBCD, and Pigment Violet 29, are on the TURA chemicals list and are subject to TURA's requirements.23 Moreover, the TURA program may designate "Higher" or "Lower Hazard Substances" within the larger TURA list of Toxic or Hazardous Substances. If a chemical is designated as a Higher Hazard Substance (HHS) under TURA, the thresholds for reporting for those chemicals are lowered. To date, the TURA program has designated 14 chemicals or chemical categories as HHS. Four of the Initial Ten TSCA Chemicals are designated as HHS under TURA: trichloroethylene, perchloroethylene, 1-bromopropane, and methylene chloride.25 Footnotes 23 That HBCD and Pigment Violet 29 are not listed does not represent any judgment of the toxicity of these chemicals. It simply means that they have not been taken up for consideration and possible addition to the TURA list and they may later be added to the TURA list. 25 That six of the Initial Ten TSCA Chemicals are not designated as HHS in Massachusetts does not mean that the TURA program considers them to be less toxic than others. Rather, it means that those chemicals have not yet been addressed under this regulatory process.
Maine regulates several of the chemicals on the list of Initial Ten TSCA Chemicals as hazardous matter and hazardous substances. In addition, Maine regulates control technology for dry cleaners using perchloroethylene.

Y
Y
Y

125	Healey_CommentAugust72018	1	Other, Policy
126	Healey_CommentAugust72018	1	Other, Policy
127	Healey_CommentAugust72018	1	Other, Policy
128	Healey_CommentAugust72018	1	Other, Policy

N/A
N/A
N/A
N/A

Maryland: Maryland regulates the manufacture, sale, use, and disposal of chemicals—including some of the substances to be addressed in EPA's initial risk evaluations—in a variety of ways. For instance, businesses engaged in the removal or encapsulation of asbestos may do so only pursuant to a license issued by the Maryland Department of the Environment—which, in turn, has prescribed strict procedures governing such activities. From 2011–2015, the CDC reports there were 258 new cases of mesothelioma in Maryland, resulting in 207 deaths.
New York: New York regulates the manufacture, sale, use and disposal of chemicals, including some at issue in the Problem Formulations, in a variety of ways. For example, New York has a de facto ban on the use of 1-bromopropane, also known as n-propyl bromide, in dry cleaning. New York will not issue an Air Facility Registration to any facility proposing to use that chemical as an alternative dry cleaning solvent as it is not an approved alternative solvent.
Oregon: Oregon has adopted, and is considering, several state-specific statutes and regulations to manage the impacts of toxic and hazardous pollutants that encompass the majority of the Initial Ten TSCA Chemicals. These programs include: • Asbestos emissions, disposal, licensing and certification requirements. From 2011–2015, the CDC reports there were 245 new cases of mesothelioma in Oregon, resulting in 223 deaths. • Air toxics permits and benchmarks for industrial facilities. In addition, Oregon is currently in the process of developing new rules on industrial air emissions that would regulate emissions based on health risks to neighboring communities. The proposed rules will regulate emissions of hundreds of chemicals, including several of the Initial Ten TSCA Chemicals: asbestos, 1-bromopropane, carbon tetrachloride, 1,4 dioxane, tetrachloroethylene, and trichloroethylene. Oregon is relying on federal guidance and expertise to help define potential health risks for communities that are exposed to these emissions and to ensure that communities are protected from cumulative risks from other potential exposure pathways. • Toxics Use and Hazardous Waste Reduction planning requirements, which apply to large and small quantity generators of hazardous waste and Toxic Release Inventory reporters. • State cleanup and remedial actions for hazardous substances, and separate rules for dry cleaning facilities with perchloroethylene (tetrachloroethylene). In addition, legacy contamination from industrial sites is still a potential source of exposure to several of the Initial Ten TSCA Chemicals. The Oregon Health Authority's Environmental Health Assessment Program evaluates potential public health risks from contaminated sites across our state. In the last year alone, the program has been asked to evaluate public health risks from sites where environmental monitoring projects detected at least one of the Initial Ten TSCA Chemicals, including 1,4 dioxane, carbon tetrachloride, methylene chloride, tetrachloroethylene, and/or trichloroethylene. • Oregon adopted the Toxic Free Kids Act in 2015, requiring manufacturers of children's products to report the presence of specific chemicals of concern in products sold in Oregon. Several of the Initial Ten TSCA Chemicals are being reported in that program, including 1,4 dioxane, methylene chloride, tetrachloroethylene, and hexabromocyclododecane. Oregon relies on information from federal agencies to evaluate potential health risks of chemicals of concern for children, to identify new chemicals of concern to add to the reporting list, and to help address cumulative risks from these chemicals through other routes of exposure.
Across all of these programs, Oregon has compiled data documenting the presence of the majority of the Initial Ten TSCA Chemicals in various environmental media. EPA must consider the full scope of impacts from these chemicals in states like Oregon in determining the scope of TSCA risk evaluations for the Initial Ten TSCA Chemicals.

Y
Y Y
Y

129	Healey_CommentAugust72018	1	Other, Policy
130	Healey_CommentAugust72018	1	Other, Policy
131	Healey_CommentAugust72018	1	Other, Policy
132	Healey_CommentAugust72018	1	General
133	Healey_CommentAugust72018	1	Exposure, PESS

N/A
N/A
N/A
N/A
N/A

Washington: The Washington State Waste Reduction Act ("WRA") was enacted "[i]n the interest of protecting the public health, safety, and the environment[.]"Under the WRA, any person generating over 2,640 pounds of hazardous waste annually is required to "prepare a plan for the voluntary reduction of the use of hazardous substances and the generation of hazardous wastes." The Revised Code of Washington 70.95C.020 provides that both dangerous waste and extremely hazardous waste "shall specifically include those wastes designated as dangerous by rules adopted pursuant to chapter 70.105 RCW." Accordingly, pursuant to RCW 70.105, the Washington State Department of Ecology ("Ecology") has designated five of the Initial Ten TSCA Chemicals as dangerous wastes subject to voluntary reduction plans.
Within Ecology, the WRA establishes an office of waste reduction (also referred to as Ecology). Ecology's duties, in part, include encouraging the reduction of hazardous waste use, coordinating with all state agency programs to provide technical assistance, and coordinating public education programs on waste reduction. Additionally, Ecology provides technical assistance in preparing plans pursuant to WRA in an effort to reduce the use of such dangerous wastes.
Ecology collaborates with many state agencies, such as the Washington State Department of Health, and works with industries and environmental stakeholders, to identify chemicals that pose the highest risks to human health and the environment. Thereafter, Ecology develops and enforces policies, toxic chemical regulations, and plans to reduce or eliminate the use of toxic chemicals.
Under Section 6(b)(4)(A) of TSCA, EPA conducts risk evaluations to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . under the conditions of use." And the term "conditions of use" is defined as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."
So, under TSCA, EPA must conduct risk evaluations to determine whether a "chemical substance" presents an unreasonable risk under the circumstances under which that substance is "intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." The plain language of the statue requires EPA to evaluate the risks of each chemical substance identified for evaluation under all circumstances for which exposures can be anticipated, including the so-called "legacy" uses, which clearly are circumstances under which these chemicals are "known . . . to be . . . used or disposed of." Without basis in law or fact, the risk evaluation scheme reflected in the Problem Formulations fails to evaluate the risks for each chemical under all circumstances for which exposures can be anticipated and by failing to do so frustrates TSCA's purposes by ignoring exposures and underestimating risks posed by the chemical substances. For example, where the hazard posed by a chemical may relate to multiple exposure pathways, ignoring one of these pathways may result in underestimating the total, cumulative risk posed by the chemical. Such underestimation may adversely impact determinations of risk to certain populations, including those who are particularly exposed or sensitive to the chemical's adverse effects. Therefore, any risk evaluations conducted under the risk evaluation scheme reflected in the Problem Formulations cannot satisfy EPA's mandate under TSCA.

Y
Y
Y
Y
Y

134	Healey_CommentAugust72018	1	Exposure
135	Healey_CommentAugust72018	1	Other, Exposure
136	Healey_CommentAugust72018	1	Other, Exposure
137	Healey_CommentAugust72018	1	RegNex, Policy

2.2
N/A
N/A
2.5.3

1. EPA is Ignoring Highly Risky "Legacy Uses," Putting Public Health and the Environment in Grave Peril. In the Problem Formulations, EPA has eliminated from its analysis many of the most important sources of chronic exposure to these toxic chemicals by defining away these exposure pathways through the agency's unjustified narrowing of the conditions of use it will consider. Most significant, perhaps, is EPA's irrational decision to eliminate so-called "legacy" uses from its evaluations. This willful ignorance is both unlawful and patently dangerous based on the hazards both to people and the environment presented by unaccounted-for exposures to any of the Initial Ten TSCA Chemicals.
Moreover, EPA is taking inconsistent and irreconcilable positions with respect to how it views conditions-of-use determinations. On February 17, 2017, the current administration's EPA announced the availability of EPA's response to a petition EPA received in November 2016 under Section 21 of TSCA from a group of organizations, including Fluoride Action Network, Food & Water Watch, and the Organic Consumers Association, asking EPA to exercise its TSCA Section 6 authority to ban the purposeful fluoridation of U.S. water supplies. In its denial of the petition, EPA interpreted TSCA's requirements for determining "conditions of use" for risk evaluations under Section 6 of TSCA as appropriately very broad consistent with the intent of Congress in reforming TSCA. In its finding issued less than eighteen months ago, EPA announced: "Unless EPA establishes an exemption under TSCA section 6(g) (whereby certain unreasonable risks may be allowed to persist for a limited period) or EPA is addressing a persistent, bioaccumulative, and toxic substance as set forth in TSCA section 6(h), the standard for an adequate rule under TSCA section 6(a) is that it regulates "so that the chemical substance or mixture no longer presents" unreasonable risks under the conditions of use. 15 U.S.C. 2605(a). Prior to the 2016 amendment of TSCA, EPA completed risk assessments that were limited to selected uses of chemical substances. The amended TSCA authorizes EPA to issue TSCA section 6 rules that are not comprehensive of the conditions of use, so long as they are consistent with the scope of such pre-amendment risk assessments. 15 U.S.C. 2625(l)(4). But EPA has interpreted the amended TSCA as requiring that forthcoming risk evaluations encompass all manufacture, processing, distribution in commerce, use, and disposal activities that the Administrator determines are intended, known or reasonably foreseen."
Following EPA's denial of the petition, the petitioners challenged the denial in federal district court. EPA moved to dismiss the federal court challenge because the petitioners did not address conditions of use other than fluoridation of drinking water. As EPA stated in its denial of the petition: "Rather than comprehensively addressing the conditions of use that apply to a particular chemical substance, the petition requests EPA to take action on a single condition of use (water fluoridation) that cuts across a category of chemical substances (fluoridation chemicals)." The court denied EPA's motion, recognizing that a citizen petitioner under Section 21 of TSCA need not evaluate all conditions of use for the chemical substance at issue. However, for TSCA Section 6 chemical substance risk evaluations by EPA, as opposed to Section 21 determinations regarding citizens' petitions, TSCA requires the agency comprehensively to address the conditions of use that apply to that particular substance. EPA's retreat from its broad interpretation of the conditions of use that must be considered under Section 6 of TSCA is both contrary to law and represents what appears to be a mere impermissible convenient reinterpretation of the statute by the agency to avoid adequately regulating chemical substances under Section 6.
2. Risk Evaluations Must Assess Exposure Pathways For All Uses, Including Those Addressed Under Other Statures. EPA is also failing to identify properly the conditions of use by not considering exposures resulting from uses of the chemical purportedly addressed within the context of other statutory schemes.

Y
Y
Y
Y

138	Healey_CommentAugust72018	1	RegNex, Exposure
139	Healey_CommentAugust72018	1	RegNex, Exposure
140	Healey_CommentAugust72018	1	Exposure

N/A
N/A
2.2, 2.5

However, EPA's charge under TSCA is to evaluate the risks from the full range of exposures in the circumstances under which the chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of, to determine whether the chemical substance presents an unreasonable risk of injury to health or the environment. Section 6(b)(4)(A) of TSCA; 15 U.S.C. § 2605(b)(4)(A) and Section 3(4) of TSCA; 15 U.S.C. § 2602(4)
The standard for an adequate rule under TSCA section 6(a is that it regulate so that the chemical substance no longer presents unreasonable risks to public health and the environment, and it necessarily follows that EPA must evaluate the potential for exposure and risk associated with perchloroethylene being regulated under those schemes, and make appropriate TSCA regulatory determinations that account for those anticipated exposures, in order to regulate the chemical as Section 6 requires.
The approach to science expressed by EPA as reflected in the Problem Formulations fails to satisfy TSCA's "best available science" standard for the quality of data that EPA must consider in preparing its risk evaluation, and TSCA's "weight of scientific evidence" standard for decision making under Section 2605. Under TSCA, Congress expressly required EPA to engage in science-based actions to prevent unreasonable risk of injury to health or the environment as result of exposures to hazardous chemical substances: (h) Scientific standards: "In carrying out section [2605] of this title . . . the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science . . . ." (i) Weight of scientific evidence: "The Administrator shall make decisions under section [2605] of this title based on the weight of the scientific evidence." (k) Reasonably available information: "In carrying out sections 2603, 2604, and 2605 of this title, the Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." EPA is failing to account for some of the most significant, generally recognized pathways of exposure in the Problem Formulations. It follows that it is impossible for EPA to satisfy the "best available science" standard because it is choosing to put on blinders and ignore some of the most meaningful data with respect to risks of exposure to the chemical substance.

Y
Y
Y

141	Healey_CommentAugust72018	1	Exposure, Policy
142	Healey_CommentAugust72018	1	Other, Policy
143	UCSF_CommentJune252018	2	Systematic Review, General

2.2, 2.5
2.2, 2.5
3

Additionally, in its evaluation of uses in the Problem Formulations EPA fails to satisfy its statutory duties to review all reasonably available information. The Problem Formulations are rife with examples of instances where it appears that EPA stopped short of complete data collection, failing to satisfy its statutory obligation to consider the information "reasonably available" to it. Unfortunately, notwithstanding Congress's express requirement that EPA use the "best available science" in regulating toxic chemicals, the Problem Formulations on their face make it impossible for EPA to conduct the risk evaluations as required in this regard. The recent overhaul of TSCA was designed to address the recognized failures of traditional risk assessment to consider the big picture of toxic chemicals exposures and address the landscape of the many uses and exposure pathways affecting different people in different ways. TSCA, as amended by the Lautenberg Act, addresses this by mandating comprehensive risk evaluations in which EPA reviews chemical substances broadly in the context of the chemical substances' known, intended, and reasonably foreseen uses across the full spectrum of potentially exposed populations. The Problem Formulations, which would restrict EPA's reviews to certain uses and exposures that do not reflect the pathways through which people and the environment are affected by these chemical substances, will not meet the express purpose of TSCA as amended and should be abandoned in this regard.
We believe that the risk evaluations that EPA proposes to conduct for the Initial Ten TSCA Chemicals, in which the agency plans to consider only a subset of the uses for which the chemical substances are intended, known or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed, fails to satisfy the requirements for risk evaluations under TSCA. We therefore urge EPA to issue revised Scopes of the Risk Evaluation for each of the Initial Ten TSCA Chemicals to address the concerns we raise above regarding the agency's unlawful approach to identifying the conditions of use as that term is properly understood under TSCA and to ensure that the data EPA considers in its risk evaluations satisfies TSCA's "best available science" standards. After conducting appropriate risk evaluations, we expect EPA will impose new protective restrictions, and in some cases bans, for at least some of the Initial Ten TSCA Chemicals.
1. EPA should improve its literature search and systematic review strategies to strengthen its evaluations and increase transparency. Overall, we strongly commend the EPA for its efforts to utilize a systematic and transparent method of research synthesis to reach a concise, strength of evidence conclusion about the human health hazard resulting from exposures to these ten chemicals. Efforts to integrate systematic review methods, including the explicit development of search terms, strategies, and inclusion/exclusion criteria beforehand, is relatively new in EPA's chemical assessment and as such, we applaud the EPA for this and its general improvements in its hazard assessment methodology. These scoping documents generally provide an important infrastructure for outlining EPA's screening approach for identifying relevant references and to document decisions made in the process of identifying the body of scientific literature that will be evaluated in the chemical assessments. To improve on this document and advance EPA's uptake of systematic review methods of research synthesis, we identify the following opportunities for improvement.

Y
Y
Y

144	UCSF_CommentJune252018	2	Systematic Review, General
145	UCSF_CommentJune252018	2	Systematic Review, General
146	UCSF_CommentJune252018	2	Systematic Review, General

3
3
3

EPA should not exclude studies based on language. EPA's search strategy is limited to English-only studies. The exclusive reliance on English-language studies may not represent the entire body of available evidence, and studies have suggested that language bias might lead to erroneous conclusions. Furthermore, when considering the inclusion or update of an existing systematic review, studies have found that language-inclusive systematic reviews (including studies in languages other than English) were of the highest quality, compared with other types of reviews. Online translation tools are readily available to allow screeners to quickly evaluate study abstracts for relevance, and therefore we recommend EPA to incorporate non-English language studies in their screening and not simply exclude these potentially relevant papers.
EPA should provide exclusion reasons for off topic citations. In the Bibliography Supplemental File for the Scope Documents, EPA has provided lists of bibliographic citations that were identified and screened from the initial literature search and the initial categorization of whether citations were on topic or off topic. We recommend EPA additionally provide exclusion reasons that were used to come to the conclusion that each citation was off topic, as this is a standard recommendation to fulfill transparency in documenting and reporting all decisions made in the study selection process. This is particularly important as EPA has proposed to do its screening in Distiller, proprietary software that presumably will not be made publicly available, raising concerns regarding the transparency and reproducibility of this screening step.
EPA should clearly document decisions related to the identification and search. For example, it was unclear how many studies were included in the first batch of studies reviewed by the senior-level technician—these decisions should be clearly specified beforehand as to the number (or percent) that will be reviewed by this independent reviewer. Furthermore, it is unclear how many studies the senior-level technical experts are reviewing generally as to their additional feedback and guidance to individual screeners. This should be more clearly stated and described beforehand in these protocols. We recommend EPA broaden the set of studies that are initially screened in the first batch to ensure consistency across reviewers and demonstrated understanding of protocol instructions by all reviewers before moving on to screening the remaining records. It is stated in the Gray Literature Search Results that individual screeners would screen and tag 10 references that would be then independently reviewed by the senior-level technical expert. However, this does not seem to be an adequate number of studies as it is a small number relative to the expected number of records that will ultimately be screened.

Y	
Y	
Y	
Y	

147	UCSF_CommentJune252018	2	General
148	UCSF_CommentJune252018	2	General
149	UCSF_CommentJune252018	2	General

N/A
N/A
N/A

I am writing to request a correction to the May 2018 EPA document “EPA’s Responses to Public Comments Received on the Scope Documents for the First Ten Chemicals for Risk Evaluation under TSCA".
On pg. 15, in response 16, comments are incorrectly attributed to the UCSF Program on Reproductive Health and the Environment (PRHE). I am pasting the text from the document below and attaching the UCSF PRHE comments 0741-0057 as downloaded from the 1-Bromopropane docket. UCSF PRHE’s comments did not recommend or reference the “Beyond Science and Decisions” project.
[pasted information]:
Other
16. One commenters shared information on the "Beyond Science and Decisions" project, a risk methods compendium as a resource for regulators and scientists on key considerations for applying selected dose-response techniques for various problem formulations, with suggested techniques and resources (0741-0057).
Response: Thank you for this comment and for the suggested resources.

We did recommend that EPA use the risk assessment approaches, methods and principles in the National Academies of Sciences report “Science and Decisions: Advancing Risk Assessment” which we reference multiple times in our comments.
I would appreciate if EPA could respond to this letter, correct this error immediately and issue a revised version of the “EPA’s Response to Public Comments” document. Please do not hesitate to contact me with any questions.

These comments are submitted on behalf of the undersigned academic, scientists, and clinicians. We declare collectively that we have no direct or indirect financial or fiduciary interest in any chemical under consideration in these risk evaluations. The co-signers’ institutional affiliations are included for identification purposes only and do not necessarily imply any institutional endorsement or support, unless indicated otherwise. We appreciate the opportunity to provide written comments on the scope of risk evaluations for the first ten chemical substances for risk evaluations pursuant to the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety of the 21st Century Act (Lautenberg TSCA). Collectively, these chemicals represent an aggregate production volume of more than 1 billion pounds a year in 2015. Some of these chemicals have assessments, and in some cases even restrictions, under other federal programs – but none of these other programs has the mandate given to EPA under the new TSCA: to comprehensively evaluate chemicals and ensure that they do not pose an unreasonable risk to human health and the environment, with special consideration to those most vulnerable amongst us. Therefore, the task ahead for EPA is critical.

These first ten evaluations are also consequential because they will be precedent setting for the implementation of evaluation of science under TSCA. The consequent health impacts of EPA’s decisions – for better or worse – will be borne by generations of American children, workers, families, and communities. With so much at stake, we welcome EPA’s engagement with the public in this process and we offer EPA concrete approaches to embed the most current scientific principles in its methods to assess the hazards and risks of environmental chemicals.

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150	UCSF_CommentJune252022	2	General/Exposure/PESS/Systematic Review
151	UCSF_CommentJune252021	2	General
152	UCSF_CommentJune252025	2	Exposure
153	UCSF_CommentJune252026	2	Exposure

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Our comments address the following main points: 1. EPA should improve its literature search and systematic review strategies to strengthen its evaluations and increase transparency. 2. EPA needs to consider aggregate exposure within and across populations; otherwise it will underestimate risk. Aggregate exposure should include legacy uses, uses where a chemical is present as a contaminant or by-product, and uses already assessed by EPA. 3. EPA appropriately identifies factors to consider to identify populations subject to greater exposures. EPA should also address susceptible sub-populations, following recommendations from the National Academies of Sciences (NAS) to identify susceptible sub-populations based on established extrinsic and intrinsic factors that increase vulnerability. 4. EPA should rely on existing IRIS assessments for hazard identification. Moving forward, EPA should complete hazard identification or add additional studies only through a systematic review process, which integrates animal, human and mechanistic evidence as recommended by the recent NAS report. 5. For risk characterization, EPA should use defaults and methods that account for the full range of risks in the population and that will form the basis of decisions that protect the public's health. 6. Confidential Business Information (CBI) claims should not be used to obscure critical data and information from the public.
We are appreciative of the opportunity to provide public input and we look forward to continuing to participate in such opportunities in the near future. Please do not hesitate to contact us with any questions regarding these comments.
2. EPA needs to consider aggregate exposure within and across populations; otherwise it will underestimate risk. Aggregate exposure should include legacy uses, uses where a chemical is present as a contaminant or by-product, and uses already assessed by EPA. In general, EPA is proposing to consider three populations for exposure assessment: 1) Occupational users and non-users; 2) consumers and bystanders; and 3) general population. We strongly recommend that EPA calculate the aggregate exposures within and across these populations-- risk will be underestimated if it does not include these real-world exposures. Exposures within a population should also be aggregated (rather than considered in isolation) in order to estimate the general population's actual exposure to the chemical—for example, through exposures from food, water and air.
Further, as shown in the Figure below, exposures must also be aggregated across populations. Consumers and workers are part of the general population – that is, since workers and consumers also eat food and drink water, they will have the same exposures as the general population, in addition to the anticipated exposures on-the-job or from consumer products. Some workers will also be consumer product users, so they have the potential to face general, consumer product, and on-the-job exposures. These specific exposure scenarios must be accounted for in EPA's exposure estimation to ensure that such individual exposures are adequately considered and integrated into the risk assessment. [p. 10 Figure Legend: EPA must assess aggregate exposures within and across all the populations for accurate exposure assessment; Figure depicts the three populations noted within a circle and possible exposures (i.e., food, water, air, products.) The consumers and bystanders population and workers and non-users population are individually encircled but the circles overlap]

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154	UCSF_CommentJune252027	2	Exposure
155	UCSF_CommentJune252029	2	Exposure
156	UCSF_CommentJune252030	2	Exposure, RegNex, Policy
157	UCSF_CommentJune252031	3	Exposure
158	UCSF_CommentJune252032	2	Exposure

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2.6.1
2.2, 2.3, 2.6

In the Introduction section of the chemical Scope documents [Section 1], EPA states that it "may consider background exposures from legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses." This falls short of the analysis required under Lautenberg TSCA. It is critical that EPA consider ongoing exposures from legacy uses and disposal, and includes these as part of the aggregate exposure assessment. Asbestos and HBCD are two examples of this, as they have enormous volumes in place in buildings and existing infrastructure. The Healthy Building Network estimates there are 66 million-132 million pounds (30,000-60,000 metric tons) of HBCD in insulation in existing buildings —these reservoirs in-place are and will continue to be critical sources of ongoing exposures. HBCD was also used in cars and furniture, which are long-lived consumer items that will continue to contribute to ongoing exposures for years to come.
When a chemical is present in products or media as a contaminant/ by-product, EPA needs to include and assess these exposures. We strongly recommend against ignoring or discounting these potential exposures routes.
Finally, in the exposure assessments for methylene chloride [p. 30 of Scope], N-methylpyrrolidone [pp. 19-20 of Scope] and trichloroethylene [p. 27 of Scope], EPA is proposing to exclude uses it already assessed. We agree that EPA does not need to re-assess these uses; these evaluations have been completed and finalized. However, unless and until such uses are banned, the exposures from these uses continue. Therefore, the new risk evaluations need to consider the contributions of these uses to exposures by using the exposure values from the previous assessments.
For the occupational exposure analysis plan, EPA states it will "Consider and incorporate applicable engineering controls and/or personal protective equipment into exposure scenarios." However, these are not realistic assumptions nor are they appropriate for public health protection. EPA's own research shows that the primary factors influencing whether a user understands label information are the users' literacy and numeracy, which frequently correlate with the users' education and income. Therefore, people with less education, lower income, and less advanced literary skills will be the most likely to not understand label instructions. These individuals already disproportionately bear the burden of exposures to multiple environmental hazards and the resulting health impacts; thereby placing further burden on this already stressed susceptible subpopulation. Further, appropriate personal protective equipment (PPE) for workers is often not provided by employers, or may not be fitted or working properly. When evaluating occupational exposures, EPA needs to take into consideration all potential and feasible routes of exposure, and should not exclude exposure routes based on assumptions of PPE and/ or exposure controls in place. These controls are not guaranteed and may change in the future, so to assume zero exposure via these routes would be inappropriate and a failure to adequately ensure health protections, especially for susceptible sub-populations as required by the Lautenberg TSCA.
In summary, EPA needs to account for all the sources of exposure or it will underestimate risk for all 10 chemicals. When analyzing aggregate exposures, "sentinel exposure" may be considered simultaneously, where appropriate. However, these are not mutually exclusive and EPA should not incorporate sentinel to the exclusion of aggregate.

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159	UCSF_CommentJune252033	2	PESS
160	UCSF_CommentJune252036	2	PESS
161	UCSF_CommentJune252037	2	PESS
162	UCSF_CommentJune252044	2	PESS
163	UCSF_CommentJune252044	2	Other, PESS
164	UCSF_CommentJune252044	2	PESS, Human Health, General

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3.EPA appropriately identified factors to consider to identify populations subject to greater exposures. EPA should also address susceptible sub-populations, following recommendations from the National Academis of Sciences (NAS) to identifiy suscepitble sub-populations based on established extrinsic and intrinsic factors that increase vulnerability. In general, EPA proposes to consider workers and occupational non-users, consumer and by-standers, and other groups within the general population in proximity to conditions of use as sub-populations who experience greater exposures. In particular, EPA has appropriately identified people who live or work near manufacturing, processing, distribution, use or disposal sites as facing greater exposures. Such communities are often low income and/ or people of color, exposed to a disproportionate share of pollution, environmental hazards, social and economic stressors. Multiple exposures to chemical and non-chemical stressors collectively increase the risk of harm, combined with synergistic effects with other health stressors in their daily lives such as limited access to quality health care.
For example, the prenatal lifestage is the most sensitive to developmental and reproductive toxicants, and women of child-bearing age should be considered as a susceptible sub-population for any chemicals with such hazards. Women of reproductive age are not specifically identified as a potential susceptible sub-population for pigment violet 29, TCE, NMP, PERC, or HBCD, even though EPA will consider reproductive and developmental toxicity hazards for these chemicals.
As discussed below, science-based defaults should be used to account for these and other susceptibilities, unless there is there is chemical-specific data available to support increasing or decreasing the default.
5. For risk characterization, EPA should use defaults and methods that account for the full range of risks in the population and that will form the basis of decisions that protect the public's health. Defaluts: We strongly support the use of health protective defaults to incorporate factors that reflect the range of variability and susceptibility in the population to ensure risks are not underestimated. The importance of using protective science-based defaults was highlighted by the NAS in 2009. The default should be used for factors that are known to influence risk unless there is chemical-specific data that support increasing or decreasing it; when there is inadequate information to quantitatively assess inter- or intraspecies differences for a specific chemical, the defaults should be used. For example, EPA's defaults should include: • Inter-human variability, general • Inter-human susceptibility to carcinogens, adult • Inter-human susceptibility to carcinogens, early life (including prenatal) • Inter-human susceptibility to non-carcinogens, early life (including prenatal) • Animal findings are relevant to humans • Findings from one route of exposure are considered representative unless data show otherwise
EPA has relied on standard default values ("uncertainty" or "safety" factors) that have been applied across the board to various chemicals and health outcomes. But newer science demonstrates that EPA's typical safety factor of 10 is insufficient to account for variability due to life stage, genetics, underlying disease status, and external stressors that may be due to poverty or other difficult life conditions.
For cancer, the NAS recommended that EPA include a factor to account for human variability in response to carcinogens, as EPA's current approach inaccurately assumes that there is no variability in response. They found that a factor of 25- to 50- may account for the variability between the median individual and those with more extreme responses, and recommended 25 as a reasonable default value.

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165	UCSF_CommentJune252044	3	PESS, Human Health
166	UCSF_CommentJune252044	2	PESS, Human Health
167	UCSF_CommentJune252044	2	Other

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Similarly, EPA should increase or add factors that address cancer and non-cancer susceptibility during early life stages. While EPA does account for increased susceptibility to genotoxicants, it does not include the prenatal period or chemicals that can influence cancer through other mechanisms. California EPA's guidance incorporates factors to account for increased susceptibility for exposures that occur prenatally for carcinogens, non-mutagenic carcinogenic agents and non-carcinogens. Their literature review on differential susceptibility to carcinogens and non-carcinogens based on age and life stage derived age adjustment values for carcinogens which include the prenatal period and increased the default intraspecies uncertainty factors for non-carcinogens to 30 and 100 for specific endpoints such as asthma or neurotoxicity. At a minimum, EPA should use Cal EPA's age adjustment values and intraspecies uncertainty factors for incorporating age/early life susceptibility.
In general, developmental life stages, including the fetus, infancy, and childhood, are more vulnerable to chemical exposure and toxicity. However, typical EPA age-dependent adjustment factors account for other life stages but NOT fetal exposures. Recent studies have demonstrated differential expression and activity of metabolic enzymes such as Cytochrome P450 in fetal versus adult tissue, indicating potential lifestage-dependent variability in metabolic capabilities and greater vulnerability during fetal development not accounted for in current risk assessment practices. This is a critical point to address, as disruptions during fetal development have implications for health and disease in adulthood. EPA should evaluate this rich body of literature to identify the most up-to-date scientific knowledge regarding human variability and susceptibility and incorporate these scientifically-based default values in their assessments unless there are chemical-specific data supporting departing from the defaults. California EPA also developed child-specific risk values for chemicals (e.g., atrazine, lead, nickel, manganese, heptachlor) that specifically address routes of exposure and differences in susceptibility unique to children compared to adults. EPA should review these evaluations and incorporate these values as appropriate. Furthermore, a default guidance principle should be that animal findings are relevant to humans unless there is sufficient and compelling information to support otherwise.
Risk Estimates: EPA should not use MOE (margin of exposure) as an analysis method in the risk evaluation process moving forward. MOE is not an estimate of risk—it is a single number that is a version of the "bright line" approach like the Reference Dose (or Reference Concentration for inhalation doses). MOE is calculated by dividing the point of departure (e.g., LOAELs, NOAELs or BMDLs) by estimated exposure values, and this 'bright line' approach does not provide information about the magnitude of the risks above, at, or below this line. Further, it implies that there is a "safe" level of exposure below which no harm will occur. While this may be true for a select few chemicals, the NAS Science and Decisions report recognizes that this is not a valid assumption for all chemicals and has recommended moving away from such "bright line" approaches which do not establish risk estimates across the full range of exposures. Additionally, the MOE will not provide the necessary information for future analysis of risks and benefits that will be critical for decision-making on these chemicals. We recommend that EPA utilize available analytical methods such as PODs based on a BMD to develop quantified estimates of risk.

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168	UCSF_CommentJune252044	2	Other
170	UCSF_CommentJune252044	2	Other
171	UCSF_CommentJune252044	2	Other
172	ACOEMCommentAugust82018	1	General
173	EPA-HQ-OPPT-2016-0737-DRAFT-0107_ACA	1	General

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EPA appropriately states that a dose-response assessment will be conducted for all identified human health hazard endpoints. PODs should also be developed for every endpoint unless the data are insufficient to develop a model. For calculating cancer or non-cancer risks, we recommend always using a point of departure (POD) of a benchmark dose (BMD) at 1%. The POD should be based on a BMD calculation, not the NOAEL/LOAEL, unless the data are insufficient to model. EPA already recognizes the features that make BMDs superior: BMDs account for the shape of the dose–response function; are independent of study design, such as the space between dosing; and are comparable across chemicals.
Historically, for carcinogens that are direct mutagens or are associated with large human body burdens, EPA has assumed there is no threshold of effect. But the NAS Science and Decisions report highlights the science indicating that this linear presumption with no threshold is appropriate for the calculation of both cancer and non-cancer risks, and regardless of whether a carcinogen is a mutagen. For example, dose-response relationships can be linear at low dose when exposures contribute to an existing disease process, add to background processes and/ or exposures, and interact with interindividual variability or susceptibility. Science and Decisions recommends harmonizing cancer and non-cancer risk assessment approaches. Therefore, for calculating non-mutagen cancer or non-cancer risks based on a POD, EPA should use the same approach as for mutagens, which assumes a straight line from the POD. In fact, a linear relationship may actually underestimate risks for some chemicals where the dose-response curve is supra-linear.
6. Confidential Business Information (CBI) claims should not be used to obscure critical data and information from the public. Production volumes for both asbestos and pigment violet 29 have been claimed as CBI. Production volume is basic information about a chemical to which the public and scientists should have access. We urge EPA to move forward with substantiating such claims under the new TSCA.
The American College of Occupational and Environmental Medicine (ACOEM) is pleased to respond to the EPA's request for comments about its planned chemical evaluation for perchloroethylene (PCE). EPA is requesting any information from the public on perchloroethylene (PCE both domestically and internationally. ACOEM represents more than 4,000 physicians and other health care professionals specializing in the field of occupational and environmental medicine (OEM). Founded in 1916, ACOEM is the nation's largest medical society dedicated to promoting the health of workers through preventive medicine, clinical care, research, and education. A dynamic group of physicians encompassing specialists in a variety of medical practices is united via the College to develop positions and policies on vital issues relevant to the practice of preventive medicine both within and outside of the workplace.
The American Coatings Association ("ACA") appreciates the opportunity to comment on proposed Problem Formulations for the first 10 chemical risk evaluations as required by the Frank R. Lautenberg Chemical Safety for the 21st Century Act ("Lautenberg Act"). We are committed to working with EPA to help ensure accurate risk evaluations under TSCA. The Association's membership represents 90% of the paint and coatings industry, including downstream users (or processors) of chemicals, as well as chemical manufacturers. Our membership includes companies that manufacture paints, coatings, sealants and adhesives whose manufacturing processes or products may be affected by the outcome of EPA's risk evaluations for several of the first ten chemicals. Similarly, our membership is concerned about EPA's process for chemical risk evaluations as established during review of this initial set of chemicals. ACA is eager to assist EPA in developing an effective system for chemical risk evaluations with successful implementation of the Lautenberg Act's mandates.

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174	EPA-HQ-OPPT-2016-0737-DRAFT-0107_ACA	1	General
175	EPA-HQ-OPPT-2016-0737-DRAFT-0107_ACA	1	Exposure
176	EPA-HQ-OPPT-2016-0737-DRAFT-0107_ACA	1	Exposure, RegNex
177	EPA-HQ-OPPT-2016-0737-DRAFT-0107_ACA	1	Exposure

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ACA applauds EPA's willingness to interact with stakeholders during this process, ensuring that the Agency is taking steps in the right direction. ACA understands that implementation of the Lautenberg Act is not clear cut, and commends EPA on the solutions they have offered thus far. We are optimistic that through continued involvement with the public and stakeholder community, EPA will be successful in implementing a stronger, federal chemicals management program for years to come.
I. Establishing Federal Pre-emption for Conditions of Use ACA generally supports EPA's reasoned evaluation and exclusion of conditions of use from risk evaluation, based on the following (as stated in EPA's problem formulations): 1) Insufficient information to include an activity as a condition of use in a risk evaluation; 2) The condition of use is adequately controlled by other federal regulatory programs and therefore excluded from final risk evaluation; and 3) The condition of use does not require further analysis, but EPA will include it in the final risk evaluation based on existing information.
Although in current risk evaluations, EPA has carefully described reasons for excluding conditions of use, ACA is concerned that a situation could arise in future risk evaluations where EPA excludes a condition of use in a manner that prevents EPA's risk evaluation from being comprehensive while limiting federal pre-emption. Under Section 18(a)(1)(B) of TSCA, states cannot establish a statute, criminal penalty or administrative action that restricts a use that EPA has made a final determination about (under Section 6(i)(1)), consistent with the scope of risk evaluation in Section 6(b)(4)(D). ACA is concerned that conditions of use relevant to the paint, coatings, sealants and adhesives industries, in future risk evaluations, will not be included in EPA's final risk evaluation. In effect, TSCA's pre-emption of state activities may not apply to such conditions of use, opening the door for a patchwork of state-level requirements. In certain instances, ACA would recommend that the Agency acknowledge uses that do not merit an unreasonable risk determination and include analysis supporting such a determination in a final risk evaluation. ACA recognizes that such an analysis would have to be made on a case-by-case basis. Similarly, ACA can also envision a situation where a condition of use is adequately controlled by an existing federal program, but EPA should nonetheless include it in the final risk evaluation to describe EPA's rationale for concluding the use poses no unreasonable risk. Such an approach might be appropriate where comprehensive mitigation of a risk factor by a federal program is uncertain or not universally accepted.
II. De Minimus Exposures and Final Risk Evaluations ACA can envision a situation where EPA could include de minimis exposures in a final risk evaluation, if only to document and integrate evidence of de minimis exposures to support a conclusion of no unreasonable risk. Such an analysis would promote comprehensive review while preserving pre-emptive effect of EPA's evaluation for the condition of use, rather than exclusion for de minimis exposures. Generally ACA supports EPA's exclusion for de minimis exposures in the current group of evaluations. For example, in its Problem Formulation for Carbon Tetrachloride, EPA excludes "industrial / commercial / consumer uses of carbon tetrachloride in commercially available aerosol and non-aerosol adhesives / sealants, paints / coatings and cleaning / degreasing solvent products" as a "conditions of use with de minimis exposure." EPA demonstrates that carbon tetrachloride is sufficiently restricted by other regulatory programs and is not a direct reactant or additive for the identified condition of use.

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178	EPA-HQ-OPPT-2016-0737-DRAFT-0107_ACA	1	Exposure
179	EPA-HQ-OPPT-2016-0737-DRAFT-0109_tire-manufacturers	1	Other/Exposure
180	EPA-HQ-OPPT-2016-0737-DRAFT-0109_tire-manufacturers	1	Exposure, Policy
181	EPA-HQ-OPPT-2016-0737-DRAFT-0109_tire-manufacturers	1	Exposure
182	EPA-HQ-OPPT-2016-0737-DRAFT-0109_tire-manufacturers	1	General/Exposure

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Apx C-1, Apx D-1
2.2.2, 2.5
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III. Conclusion Noting these concerns for future evaluations, ACA supports EPA's identification of uses for inclusion and exclusion in the current set of problem formulations, while clearly distinguishing uses EPA will include in final risk evaluations without further analysis from those uses EPA will not include in final risk evaluations. ACA encourages EPA to continue its careful case-by-case analysis of conditions of use. ACA will submit comment in the future as appropriate.
III. General comments on EPA's approach to problem formulations. A. Supporting tables. USTMA appreciates the supporting tables in the appendices for the various problem formulations for the first ten chemicals EPA will review. For TCE, these are "appendix C - SUPPORTING TABLES FOR INDUSTRIAL AND COMMERCIAL ACTIVITIES CONCEPTUAL MODEL" and "appendix D -SUPPORTING TABLE FOR CONSUMER ACTIVITIES AND USES CONCEPTUAL MODEL." These tables clearly communicate the uses of a chemical and the various routes of exposure EPA will assess in risk assessment. USTMA encourages the agency to continue use of these tables in problem formulation documents.
B. Conditions of use. USTMA supports EPA's exclusion of uses outlined in the market and use report that are either past uses or uses that the agency does not have enough information to confirm the use of a substance. However, USTMA questions EPA's approach for each of the first ten chemicals to exclude certain exposure pathways that are under the jurisdiction of other regulatory programs; specifically, the Clean Water Act (CWA). USTMA encourages EPA to assess the scope of the CWA in regulating non-point sources. USTMA supports a robust federal approach to review aquatic routes of exposure versus a state-by-state approach for addressing non-point sources. Additionally, the problem formulation documents specify that EPA "may exclude conditions of use that the Agency has sufficient basis to conclude would present only de minimis exposures or otherwise insignificant risks (such as in a closed system that effectively precludes exposure or as an intermediate.)" U.S. Environmental Protection Agency, Document #EPA-740-R1-7014, Problem Formulation of the Risk Evaluation for Trichloroethylene (May 2018) at 19. USTMA encourages EPA to ensure the preemptive effect of TSCA by providing a safety determination for de minimis uses. For example, EPA could conclude that there is no unreasonable risk presented by the de minimis use of a chemical substance because the substance is in a closed loop system, a chemical intermediate or an impurity.
C. "Fit for purpose" The problem formulations for the first ten chemicals specify that each risk evaluation will be "fit-for-purpose," meaning that "not all conditions of use will warrant the same level of evaluation and the Agency may be able to reach some conclusions without comprehensive or quantitative risk evaluations." (Problem formulation for TCE at Page 13). USTMA supports a screening level approach to risk evaluation and conclusion that "not all conditions of use will warrant the same level of evaluation." We also support the agencies decision to "reach conclusions without comprehensive or quantitative risk evaluations." USTMA encourages EPA to issue safety determinations for uses as they are made by the agency. We support and encourage the agency to issue safety determinations about uses that do not pose a risk early in the risk evaluation process.
IV. Conclusion. USTMA thanks EPA for the opportunity to provide comments on the problem formulation process and accurate information on the use of TCE, one of the first ten chemicals under review through the Toxic Substances Control Act as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

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183	EPA-HQ-OPPT-2016-0737-DRAFT-0111_UAW	1	General
184	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General
185	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General
186	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General
187	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General, Editorial
188	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General, Editorial

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The International Union, UAW, representing one million active and retired members is grateful for the opportunity to comment on the above referenced document.
The City of New York (City) submits these supplemental comments regarding the above referenced Problem Formulations for Risk Evaluations for 10 chemicals (Problem Formulations) issued by the Environmental Protection Agency (EPA) on June 11, 2018 pursuant to Section 26(n)(2) of the Toxic Substances Control Act (TSCA), as amended in 2016 by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Chemical Safety Act). On July 13, 2018 the City submitted an initial set of comments and made a request for a four month extension of the deadline by which comments must be submitted. EPA provided an extension of the date by which comments must be submitted, from July 26, 2018 to August 16, 2018.3 The City now raises additional significant concerns and reiterates its request for an extension to review the Problem Formulations.
A. The City's Procedural Concerns. The ten Problem Formulations are complex technical documents that cumulatively are over 1,200 pages (not including the 2017 scoping documents). While EPA did grant an extension of the comment period from July 26, 2018 to August 16, 2018, the cumulative comment period of sixty-six days to review these materials is insufficient. Their complexity and length alone warrants a further extension of the comment period.
Further, EPA's choice to develop new Problem Formulations instead of amending their June 2017 scoping documents has resulted in inconsistencies between the documents that make them difficult to compare. Additionally, these scoping documents are not easily found on the regulations.gov sites for the individual Problem Formations for the 10 chemicals, and links are not available on the global website for the Problem Formulations. While EPA accounts for this choice by claiming they lacked sufficient time, it is unclear why that is the case. 7 Footnote: 7 As explained in the Scope Document, because there was insufficient time for EPA to provide an opportunity for comment on a draft of the scope, as EPA intends to do for future scope documents, EPA is publishing and taking public comment on a problem formulation document to refine the current scope, as an additional interim step prior to publication of the draft risk evaluation for trichloroethylene.".
For example, Trichloroethylene (TCE) and Tetrachloroethylene (PERC) are among the most well-studied chemicals and are among those pollutants most prevalent in groundwater in the U.S. and elsewhere. It appears that the only difference between the scoping document and the Problem Formulation documents for these chemicals is that they have "refined" the conditions of use and exposure pathways, eliminating certain conditions of use and exposure pathways from consideration. It is unclear why these changes warranted a whole new document that impedes transparency, as it is difficult for the public to compare the Problem Formulations to the 2017 scope in order to understand the differences. It would be more helpful and easier for the public to understand any differences if EPA simply called the Problem Formulations amended scoping documents, rather than giving them new names and formats, insofar as scoping is an accepted mechanism to formulate problems for consideration in analysis.
Additionally, EPA should make the scoping documents more easily accessible to the public, and provide explicit explanations of the differences between the scoping documents and Problem Formulations.

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189	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General
190	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General
191	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General, Editorial
192	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure
193	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure
194	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure

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2.2.2, 2.3.5
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Additionally, TSCA requires EPA to "publish the scope of the risk evaluation to be conducted" but does not specifically require EPA to issue a problem formulation. Specifically, TSCA directs EPA to include in its scope the "hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider," while EPA purports to now do this in the Problem Formulations. However, because the statute directs the public to look at the scopes for this information, and not to problem formulations, interested stakeholders may not clearly understand revisions to the scope set forth in these Problem Formulations.
If, as stated by EPA "[t]he first 10 problem formulation documents are a refinement of what was presented in the first 10 scope documents" then EPA's assertion that "TSCA § 6(b)(4)(D) does not distinguish between scoping and problem formulation" is incorrect and contrary to law—TSCA Section 6(b)(4)(D) does not distinguish between scoping and problem formulation because it provides no explicit requirement for the publication of a problem formulation at all. This approach contradicts the Administrative Procedures Act by rebranding the scoping document into a Problem Formulation document, complicating and preventing the public from fully understanding the changes being made.
The City again requests that EPA fix certain inadequacies in its docket, restart the comment period, and provide a four-month extension of the comment period to allow for additional public outreach and education. [Attachment A; comments dated 7/13/18] Additionally, because EPA does not clearly lay this out, the Agency suggests that it expects to continue to follow this process in the future, and the City of New York requests herein that any documents that EPA considers to have a scoping purpose be titled as a scope, show all revisions made to the new document that differ from any prior scope or problem formulation, and have those changes and all supporting documents easily available to the public.
B. The City's Substantive Concerns EPA is subject to TSCA's statutory directive to "regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards" and to "consider the environmental, economic, and social impact of any action the Administrator takes or proposes as provided under this chapter." EPA's failure to consider legacy exposure, as well as exposures that occur as a result of pathways that are not conditions of use, is arbitrary and capricious.
1. Legacy Contamination In addition to the City's concern about EPA's decision to remove from the risk evaluation certain activities and exposure pathways discussed below, the City is also concerned with excluding legacy uses from Problem Formulations and risk analyses. [p. 8-9, 20-21 of PF for asbestos] Many of the 10 chemicals have been used extensively in New York City, and are part of our built environment. The risks of exposure from legacy uses and disposal of these substances is noteworthy and ongoing.
By disregarding the risks of legacy uses of all 10 chemicals, most importantly asbestos, PERC, methylene chloride, carbon tetrachloride, and TCE, EPA is excluding from its consideration the means by which many Americans may be exposed to these hazardoussubstances, and undercounting the net risks of exposure for all Americans.

Y
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Y

195	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure
196	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure
197	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General
198	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General
199	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General, Editorial

2.2.2, 2.3.5
2.3, 2.6.1.1
N/A
N/A
N/A

2. Unduly Narrow Scope In many other ways, EPA's Problem Formulation has an unduly narrow scope of consideration. For example, EPA is also excluding from consideration all uses of asbestos not specifically identified by EPA, since EPA considers the use of asbestos in such "unspecified activities" as "not reasonably foreseen in the United States." To the contrary, asbestos continues to make its way into a variety of unexpected products—for example, children's crayons sold in the United States recently tested positive for asbestos. Similarly, although the Problem Formulation acknowledges that New Jersey identifies talc-containing asbestos as a hazardous substance, EPA does not discuss the risks of asbestos in talc at all.

Generally, before determining that a pathway for a given media is not an exposure risk, EPA should cite data regarding the chemical's presence or absence in the media of potential concern and revisit that determination to ensure that future exposures do not arise. Additionally, minimal risk levels can change over time. Following heightened concern about Per- and Polyfluoroalkyl compounds (PFAS) caused by the documented presence of PFAS in biosolids and in surface waters and soils following biosolid applications, EPA reduced its Health Advisory for PFASs to the 70 part per trillion range. Should EPA reduce advisory levels for any chemicals regulated under TSCA, EPA should be required to revisit exposure pathways that had earlier been discounted because of a chemical's minimal presence.

C. Conclusion EPA is arbitrarily excluding several pathways from consideration in the Problem Fonnulations, including pathways that are addressed by other federal statutes, pathways caused by legacy uses, and pathways that do not relate to conditions of use, such as exposure to people who live or work in spaces that are co-located with or adjacent to facilities that use TSCA regulated chemicals. If people are exposed to the 10 chemicals as a result of several different pathways, then eliminating certain pathways from consideration will fail to accurately account for receptors' total exposure, thereby resulting in regulations that are insufficiently protective. This failure is exacerbated by the EPA's lack of transparency in describing the differences between these Problem Formulations and the initial 2017 scoping documents.
Therefore, the City requests that EPA revise the Problem Formulations to include the aforementioned pathways, and any others that are similarly necessary to adequately evaluate exposure risk, republish the Problem Fonnulations as amended scoping documents, clearly identifying all revisions, and start the public comment period.

The City of New York (City) submits initial comments regarding the above-referenced Problem Formulations for Risk Evaluations for 10 chemicals (Problem Formulations) issued by the Environmental Protection Agency (EPA) on June 11, 2018 pursuant to Section 26(n)(2) of the Toxic Substances Control Act (TSCA), as amended in 2016 by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Chemical Safety Act). The City has significant concerns about the Problem Formulations, which ignore certain exposure pathways that are common in New York City, and therefore may result in regulations that will put New Yorkers at risk. These concerns are addressed more fully below. [Attachment A; comments dated 7/13/18]

In addition, the City requests that EPA fix certain inadequacies in its docket, restart the comment period, and provide a four-month extension of the comment period to allow for additional public outreach and education, the development of a complete and navigable docket, and further consideration of the complex regulatory and scientific issues implicated in the Problem Formulations. [Attachment A; comments dated 7/13/18]

Y
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Y
Y

200	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure
201	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure
202	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure

2.2.2, 2.3.5
2.2.2, 2.3.5
2.2.2, 2.3.5

A. The City's Substantive Concerns The Problem Formulations relate to ten different chemicals used across a spectrum of applications and industries, many of which (including, Methylene chloride, Perchloroethene, and Trichloroethene) are used frequently in the City in facilities that, because of our dense urban environment, are co-located in or adjacent to buildings where other people, including sensitive receptors, use the buildings for residential or commercial purposes. Others are currently used with less frequency, but off-gas into the air of buildings because they are present in soil vapor or groundwater (for instance, Carbon tetrachloride and 1-Bromopropane). For instance, dry cleaners are often in residential buildings where children may live or be cared for, or next to schools. Often, these chemicals are used in mixed-use zoning districts where residential and commercial uses are permitted to exist adjacent to or co-located with manufacturing uses. Because of these uses, the City is concerned about the limitations that EPA has set forth in the Problem Formulations that exclude from consideration certain exposure pathways. [Attachment A; comments dated 7/13/18]
First, the City has significant concerns about EPA's decision to remove from the risk evaluation certain activities and exposure pathways, including "activities that EPA concluded do not constitute conditions of use." [p. 21 of PF for PERC] This limitation deviates from the scope set forth in the June 2017 Scopes of Risk Evaluation, [Scope for PERC] which stated that EPA intended to "assess each use subcategory by identifying all potential sources of release and human exposure associated with that subcategory." [pp. 20-21 of Scope for PERC] By excluding activities and uses that are designated on a case by case basis as not constituting conditions of use,4 EPA will likely fail to consider potential exposures caused during manufacture and use of the product, such as accidental spills, or exposures that occur when the chemical is used properly when the facility is co-located with or adjacent to residential, educational, recreational, or commercial activities. For example, using trichloroethene (TCE) as a spot remover in a co-located dry cleaning facility on the ground floor may result in a resident on the floor above the facility being exposed to the TCE. [Attachment A; comments dated 7/13/18] Footnote: 4 "Conditions of use" are defined by the Administrator and he or she has the authority to exclude conditions on case-by-case basis.
Moreover, what is currently considered "proper use" of a chemical may change in the future. Painting walls with lead-based paint or using PCBs for myriad purposes in the 1950s was proper use, but we are still dealing with the ramifications of those uses today. TSCA was amended by the Chemical Safety act to ensure that the potential problems of chemicals would be recognized before they go into widespread commercial or industrial use or, for current chemicals, to reduce the current impacts. By excluding many avenues of exposure from evaluation, EPA may allow these problems to continue, or be exacerbated. [Attachment A; comments dated 7/13/18]

Y
Y
Y

203	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure, RegNex
204	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure
205	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General
206	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General

2.2.2, 2.3.5
2.2.2, 2.3.5
N/A
N/A

Second, the City objects to EPA's exclusion of "exposure pathways [covered] under regulatory programs of other environmental statutes, administered by EPA, which adequately assess and effectively manage exposures and for which long-standing regulatory and analytical processes already exist, i.e., the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA) and the Resource Conservation and Recovery Act (RCRA)." [p. 54 of PF for PERC] While other governing statutes often address the same chemicals as TSCA regulations, they are often (if not exclusively) most effective in regulating contaminants after they are already in soil, water and air, or are focused on controlling discharges at a pipe or stack. These statutes often cannot prevent contaminants from entering the water, air, or soil in the first place, and are not intended to, and do not, ensure that chemical products are used safely and effectively. By failing to consider exposure pathways that result from spills or potential consequences of proper use that cause a chemical to enter the water, air, or soil, EPA will fail to properly account for exposures to the public, including New Yorkers, that result from TSCA-regulated activities. [Attachment A; comments dated 7/13/18]
Under both New York City's Community Right to Know Law, Local Law 26 of 1998, and Spill Bill, Local Law 42 of 1987, the City makes a concerted effort to educate facility operators on good housekeeping practices to prevent releases of chemicals from occurring. These local laws have helped protect City residents by monitoring facility owners and operators to ensure the safe and proper use of chemicals, and have served to protect the public and property from such chemical releases in the environment. However, the City's efforts must be complemented by EPA regulatory measures that set protective limits on the manufacture and use of these chemicals. These Problem Formulations have the effect of minimizing consideration paid by EPA to sensitive receptors' exposures. By intentionally turning a blind eye to the impacts on sensitive receptors, EPA risks frustrating enforcement of Local Laws 26 and 42, which the City has been enforcing for 30 years. If EPA were to weaken its regulation of these chemicals based on Project Formulations that don't sufficiently account for exposures to people who spend time adjacent to or co-located with regulated facilities, EPA is effectively undermining the City's ability to effectively protect the public and environment. [Attachment A; comments dated 7/13/18]
B. The City's Request for an Extension The City also notes, and objects, that the Federal Register directs the public to the docket at regulations.gov for access to materials relevant to the Notice and Problem Formulations but the docket is incomplete. For example, a recent search for the document titled "Application of Systematic Review in TSCA Risk Evaluations"7 did not identify the document on the docket. City staff contacted the relevant EPA contact listed in the Federal Register, who expressed surprise to learn that the document was not on the official docket web page. However, the document was still missing from the docket upon submission of these comments, and in any event, even if it were posted belatedly, it would not be available for the full comment period. [Attachment A; comments dated 7/13/18] Footnote: 7 While this document is not available on the official docket, it can be identified by an internet search.
Additionally, at the time of these comments, although some of the other docket numbers for the specifically referenced ten chemicals contained links to record documents, some did not, creating confusion. For example, Docket number EPA-HQ-OPPT-2016-732-0080, for PCE, shows the Problem Formulation document, but indicates that the comment period has closed. However, the Problem Formulation document is dated May 2018 and was posted in June 2018. [Attachment A; comments dated 7/13/18]

Y
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Y
Y

207	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General, Editorial
208	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	General
209	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	General
210	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	General

N/A
N/A
N/A
N/A

Considering that the docket is not complete, that there are five separate docket numbers assigned to various aspects of the Chemical Safety Act, and that EPA's website is confusing to the general public, it is unclear what EPA is soliciting comments on, where those and related documents are located, and when comments are due. EPA has not complied with required administrative procedures for public notice and comment. Illustrative of these issues, as of July 10, 2018 there were only two comments on record on regulations.gov, despite the significant numbers of people affected by the Project Formulations, which indicates that there has not been sufficient public outreach and education. Consequently, we request that EPA fix the inadequacies in its docket. We further request that EPA restart the comment period and provide a four month extension because the Project Fonnulations themselves are extraordinarily complex, and therefore, the consequences of their conditions and limitations demand diligent review that cannot be accommodated within the 45-daycomment period. [Attachment A; comments dated 7/13/18]
On behalf of North America's Building Trades Unions (NABTU), its fourteen affiliated national and international construction unions and the three million working people they represent, I am writing to provide comment on the Problem Formulation of the Risk Evaluation Documents for the priority chemicals. NABTU urges the EPA to examine the full range of risks that current exposures to the priority chemicals are posing to construction workers and the public. Construction workers are exposed to the priority chemicals and a comprehensive risk assessment is required to effectively understand how best to manage unreasonable health risks. NABTU's comments on EPA's New Chemicals Review Program under the Amended Toxic Substances Control Act (EPA-HQ-OPPT-2017-0585-0056) are attached.
These comments are submitted by North America's Building Trades Unions (NABTU) on behalf of its 14 affiliated national and international construction unions and the 3 million working men and women they represent. Many of these workers are regularly employed in building, maintaining, renovating, or demolishing structures, work that exposes them to a variety of products and chemicals. On behalf of these workers, NABTU is submitting comments on the Environmental Protection Agency's (EPA's) Problem Formulation of the Risk Evaluation Documents to urge EPA to examine the full range of risks that current exposures to priority chemicals are posing to construction workers and the public.
In 2016, through bipartisan effort, Congress passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act, reforming the Toxic Substances Control Act (TSCA). Congress amended TSCA because it understood that although the statute had been on the books since 1976, toxic substances continued to pose substantial risks to the public. Congress directed EPA to quickly assess whether "the manufacture, processing, distribution in commerce, use or disposal" of known toxic chemicals "presents an unreasonable risk of injury to health or the environment," including to "potentially exposed or susceptible subpopulations," in all of their "conditions of use." § 6 (a) and (b)(4)(A). In selecting toxins to assess, EPA is to start with "high-priority substances," defined as those that, "without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment." § 6(b)(1)(B). And if EPA finds that a particular toxic substance poses an unreasonable risk, it is to take action to limit or prohibit its use. § 6(a).

Y
Y
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Y

211	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	General
212	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure, PESS
213	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure, PESS
214	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure, PESS
215	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure, PESS

N/A
2.3.5
2.2, 2.3.5
2.2, 2.3.5
2.2, 2.3.5

EPA has identified ten high-risk, high priority chemicals to be the first evaluated and regulated under the Frank R. Lautenberg Chemical Safety for the 21st Century Act: 1-bromopropane (1-BP), 1,4-dioxane, carbon tetrachloride, cyclic aliphatic bromide cluster (HBCD), methylene chloride, n-methylpyrrolidone (NMP), pigment violet 29, tetrachloroethylene (PERC), trichloroethylene (TCE), and asbestos. The group of these chemicals is referred to as the 'priority chemicals'. These comments focus on the priority chemicals; however, NABTU has submitted additional comments specific to asbestos.
Construction workers are routinely exposed to many of the priority chemicals. The amendments to TSCA require EPA to assess the risks chemicals pose "to health or the environment," including to the health of "potentially exposed or susceptible subpopulation[s]." §6(b)(4)(A). NABTU fully supports EPA's decision to include worker exposures in the scope of the risk assessment as discussed in the Problem Formulation documents. However, as discussed in more detail below, we are concerned that several of the decisions EPA has made in its Problem Formulation for the 10 priority chemicals will undermine its ability to fully assess the risks these chemicals pose to construction workers.
As presented in previous NABTU comments concerning the scope of the risk assessment for the priority chemicals (e.g., EPA-HQ-OPPT-2016-0723-0006), construction workers are regularly exposed to a variety of chemicals, including the priority chemicals. Construction workers are exposed to the priority chemicals through an array of products, including adhesives, coatings, cleaning products, degreasers, lubricants and greases, cures and sealants, strippers, cutting and metalworking fluids, refrigerant flushes, insulations, surfactants, concrete admixtures, soldering flux, and welding anti-spatter. Construction workers often apply these chemicals in inclosed or poorly ventilated areas (e.g. stripping paint in an enclosed room) or under hot conditions (e.g. applying roof coatings in the summer) which can increase the risk for high level exposures.
Moreover, construction workers are often unaware that they are being exposed to these toxins. First, they may not know that products they are using contain these chemicals. And second, they may not even be aware that the products are in their work environment. Construction sites are complex operations with multiple trades coordinating and performing work in the same vicinity. Therefore, workers routinely encounter exposures generated by other trades, without necessarily being aware of or familiar with the attendant hazards. Additionally, construction workers routinely perform maintenance, renovation, and upgrade work in industrial facilities. These work setting pose additional challenges to the ones described already, in that chemical, energy, and manufacturing facilities use tens of thousands of chemicals and mixtures, all of which may not be communicated to the contracted workforce. These "bystander" exposures are an important route for EPA to consider when evaluating risk.
The wide variety of chemicals to which construction workers are exposed is evident from a pilot study completed by CPWR - The Center for Construction Research and Training in January 2018. The pilot study asked 196 safety and health trainers from four different construction unions to identify common chemical hazards encountered in their trades. The trainers identified 63 different common chemical hazards in their trade, including some of the priority chemicals. The results were instructive, as they revealed not only the large numbers and wide range of chemicals which construction workers regularly encounter, but they showed that even these well-informed trainers did not necessarily know which specific chemicals are present in the products they use. For example, while almost two thirds of trainers listed adhesives as a common hazard, less than one fifth reported 1-bromopropane, methylene chloride, perchloroethylene, or trichloroethylene as a common hazard, even though these chemicals are known components of some adhesives.

Y
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Y
Y

216	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure
217	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure, Policy
218	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure
219	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure, PESS

2.2, 2.3.5
2.2, 2.5
2.3.5, 2.5.3
2.2.2

A comprehensive risk assessment is required to protect potentially exposed and susceptible subpopulations. The statute directs the Administrator to "conduct risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . under the conditions of use." §6(b)(4). Congress clearly intended the Administrator to assess the risks chemicals pose throughout their entire lifecycle, by defining the conditions of use to include all of the circumstances "under which a chemical substance is intended, known or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of." §3(4). Similarly, the statute specifies that the Administrator is to issue regulations addressing any "unreasonable risk" presented by the "manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or . . . any combination of such activities." §6(a).
The Problem Formulation Documents show that EPA understands that a full risk assessment model includes considerations of all the uses, pathways, and routes that pose the greatest risk of injury to the health of potential "receptors." See, e.g., Figures 2-2, 2-3, and 2-4 of each Problem Formulation Document. The agency, however, has decided to exclude from its risk assessment certain aspects of the chemicals' life cycles that are particularly important sources of exposure for construction workers. For example, as NABTU has described in detail in its comments on the Problem Formulation Document for Asbestos, excluding from "conditions of use" any "legacy uses" of the priority chemicals will eliminate evaluation of significant sources of exposure for construction workers. See NABTU comments submitted under EPA-HQ-OPPT-2016-0736. In addition, EPA must evaluate exposures from known and reasonably foreseeable "conditions of use" in addition to intended uses. EPA has decided not to evaluate exposures from many commercial uses of various chemicals stating that the products are not advertised for consumers. See e.g., Problem Formulation Document for 1-BP at 19. However, despite how a product is advertised, it may be used by consumers, particularly small contractors. This is an important source of exposure as businesses with one to nine employees made up 81% of the construction industry in 2012.
EPA has chosen to not evaluate exposures from ambient air, drinking water, ambient water, or disposal pathways. See e.g., Section 2.5.3.2 or 2.5.3.3 of the Problem Formulation Documents. In addition to occupational exposures, construction workers are individuals who live in communities, sometimes near worksites, breathing, cooking, drinking water, and enjoying time with friends and families outdoors. Ignoring these pathways ignores the home and community aspect of a worker's life.
EPA's decision not to assess products contaminated by the priority chemicals similarly eliminates a source of exposure for construction workers. Construction workers also are routinely called upon to use contaminated products, clean up contaminated environments, or remove structures built with contaminated products. Each of these tasks can generate chemicals and contaminated dusts, which is inhaled, absorbed through the skin and taken home on clothing. EPA cannot determine that these types of exposures would "present only de minimis exposure or otherwise insignificant risk" and should be excluded from evaluation without providing science-based evidence. See e.g., Problem Formulation Document for 1-BP at 21. Additionally, while contaminated products may not be an intended use, they are a "known or reasonably foreseeable use." §3(4). Worker exposures to contaminated products must be included in the scope for a comprehensive risk assessment of the priority chemicals to which construction workers, as a susceptible subpopulation, are reasonably expected to be exposed.

Y
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Y

220	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure, Policy
221	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	RegNex
222	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	RegNex, PESS

2.2, 2.3.5
2.2, 2.6
2.2, 2.6

Narrowing the uses and pathways used to evaluate risk makes it less likely that risks needing to be controlled will be identified and addressed. Aggregate, long-term exposures resulting from multiple uses and pathways in addition to timing, frequency, context, location, duration, and magnitude are the basis of chronic disease risk assessment. These concepts have long been acknowledged and evaluated in both environmental and occupational health. EPA cannot make a predetermined conclusion that there is ' no risk' prior to a risk assessment as it has in the examples discussed in these comments. Ensuring that EPA has the knowledge to adequately control risk after a comprehensive risk assessment is the only way to effectively manage health risks.
Other regulatory authorities do not justify forgoing the risk assessment mandated by TSCA. In its Procedures for Chemical Risk Evaluation Under the Amended TSCA (chemical evaluation procedures), EPA suggested that, "[d]uring the scoping phase, [it] may . . . exclude a condition of use that has been adequately assessed by another regulatory authority, particularly where the other agency has effectively managed the risks." 82 FR 33729. The chemical evaluation procedures further elaborate in Unit III.B.2 that an exposure may be excluded from evaluation if there is "a basis to foresee that the risk from the impurity would be 'de minimis' or otherwise insignificant." 82 FR 33730. However, the TSCA amendments require EPA to conduct a risk assessment before ceding responsibility to another regulatory agency or taking action itself under another of the statutes it administers. Moreover, there is no way EPA can determine whether another agency has "effectively managed the risks" or there is 'de minimis' exposure without first assessing the nature of the risks. NABTU therefore urges the agency not to exclude any pathways from its risk assessments because of the potential that the chemical may be regulated through other regulatory processes.
The EPA administers a series of statutes intended to protect the health and safety of the public and the environment from toxic chemicals, including the Clean Water Act, Clean Air Act, Safe Drinking Water Act, Resource Conservation and Recovery Act, and Toxic Substances Control Act. Congress nonetheless amended TSCA in 2016, recognizing that despite these acts, and despite authority other regulatory agencies have over occupational and environmental pollutants, the public and environment were not adequately protected. Indeed, of particular resonance to NABTU and its affiliates, disproportionate health effects have been seen in worker populations, working families, and the public who live near worksites or other contaminated areas. Through the Lautenberg Act, Congress called on EPA to conduct comprehensive risk assessments to determine whether chemicals present unreasonable risk of injury to health of potentially exposed or susceptible subpopulations, and then, based on those assessments, to determine how best to address those risks.

Y
Y
Y

223	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	RegNex
224	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	RegNex
225	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	RegNex, PESS
226	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	RegNex, PESS
227	EPA-HQ-OPPT-2016-0737-DRAFT-0113_CEH	1	Exposure, PESS

2.2, 2.6
2.2, 2.6
2.2, 2.6
2.2, 2.6
2.3

Congress gave the Administrator a number of options for addressing identified risks, including requesting that another regulatory agency take action (§9(a)) or taking action under other statutes EPA administers (§9(b)). However, that is a determination the Administrator is to make after first "determin[ing] that [there is] a risk to health or the environment associated with a chemical substance or mixture . . . ." It is only after conducting the necessary risk assessment that the Administrator may then consider whether the risk "may be prevented or reduced to a sufficient extent by action taken" either by other federal agencies or by EPA, under other federal laws it administers. If the Administrator believes another agency can adequately address the hazard, he is to submit a report to that agency, describing the risk and recommending a course of action – and if the other agency declines to act, the Administrator is required to do so. §9(a). If the Administrator determines instead that EPA has authority to address the identified risk under another of the statutes it administers, he is to decide under which statute he can best serve the public's interest. §9(b).
Thus, the Act gives the Administrator discretion to determine how to effectively address risk, only after a risk assessment is done can the EPA scientifically determine whether other regulatory authorities have adequately prevented unreasonable risk to health of the populations protected under TSCA. In fact, EPA should evaluate the risk of the priority chemicals and then as a last step consult with other regulatory authorities in order to determine how to best manage health risks and effectively protect the public.
In previous comments to EPA, NABTU discussed OSHA's limitations to protecting workers and the public to the level of protection TSCA demands from EPA. See Attachment A, EPA-HQ-OPPT-2017-0585-0056. TSCA provides EPA and OSHA co-authority over chemical exposures in the workplace. EPA should exercise its authority by consulting with OSHA to ensure that, in performing its risk assessments, occupational exposures are taken into consideration and understood, and that workers are adequately protected. In determining how to address unreasonable risks, EPA also needs to take into account that OSHA has limited resources and a high burden of proof for both creating and enforcing occupational standards.
Conclusion Construction workers are exposed to a wide variety of chemicals in conditions that can contribute to high exposure levels. The amendments to TSCA require EPA to undertake a two-step process in addressing toxic chemicals: first assess the chemical to determine whether it poses an unreasonable risk; and then determine how best to address that risk. EPA must therefore must complete a comprehensive risk assessment that includes the full life cycle of chemicals and contamination exposures to effectively understand how best to manage unreasonable health risks. Moreover, EPA cannot predetermine that other authorities effectively manage risk before completing a comprehensive risk assessment. EPA should evaluate a chemical's risk to injury the health of potentially exposed and susceptible subpopulations and then determine under which authority can effectively prevent unreasonable health risks.
2. The problem formulation must require aggregate exposure assessments that include exposures caused by conditions or products not regulated by TSCA. While exposures from current use of products is important, exposure assessments must include aggregate exposure via contaminated water, soil and air, and products that are no longer manufactured but are still in use, regardless of the source of this contamination. Aggregate exposure assessment is widely used in risk assessment. Failure to use an aggregate exposure assessment could significantly underestimate exposure, including the exposure to vulnerable subpopulations. The use of aggregate exposure assessment was recommended to the Environmental Protection Agency by the agency's Children's Health Protection Advisory Committee.

Y
Y
Y
Y
Y

228	EPA-HQ-OPPT-2016-0737-DRAFT-0113_CEH	1	Human Health, PESS
229	EPA-HQ-OPPT-2016-0737-DRAFT-0113_CEH	1	General, Policy
230	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General
231	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General

2.3.5, 2.5, 2.6
N/A
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N/A

3. The problem formulation must require use of lifestage analysis when assessing risks to children. Each stage of childhood and adolescence differs from each other and from adults in significant ways. Lifestage analysis incorporates differences in anatomy, physiology, toxicokinetics, diet, environment, and behaviors that are relevant in a risk assessment. The Environmental Protection Agency developed a framework for lifestage analysis in 2006 and the use of lifestage analysis was recommended to the Environmental Protection Agency by the agency's Children's Health Protection Advisory Committee.
7. Problem formulations are not an authorized step in the TSCA risk evaluation process and cannot be used to revisit issues of scope after the Agency has issued a scoping document. The problem formulations on the 10 chemicals are unlawful under TSCA because they go far beyond the scoping documents in excluding uses, exposures and hazards from the risk evaluations.
Comments of Safer Chemicals Healthy Families et al. on Risk Evaluation Problem Formulation Documents for Ten Chemical Substances under the Toxic Substances Control Act Safer Chemicals Healthy Families (SCHF) and the undersigned groups submit these comments on the problem formulations developed by the Environmental Protection Agency (EPA) on the initial 10 chemicals selected for risk evaluations under the newly enacted Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA). SCHF leads a coalition of national and grassroots organizations committed to assuring the safety of chemicals used in our homes, workplaces and the many products to which our families and children are exposed each day. SCHF and its partners took a leadership role during the LCSA legislative process, advocating the most protective and effective legislation possible to reduce the risks of toxic chemicals in use today. These comments address crosscutting legal and policy issues common to the 10 chemicals as well as several chemical-specific issues. We are submitting our comments to all ten of the EPA dockets. The comments build on earlier SCHF submissions, including our September 19, 2017 comments on the EPA scoping documents on the 10 chemicals. Many SCHF partner organizations are also commenting on the problem formulations and we support these comments.
Organizations joining these comments are: Alaska Community Action on Toxics, Alliance of Nurses for Healthy Environments, Asbestos Disease Awareness Organization, Center for Environmental Health, Clean and Healthy New York, Clean Production Action, Clean Water Action (National), Clean Water Action (Connecticut), Colorado PIRG (CoPIRG), Earthjustice, Environmental Health Strategy Center, Healthy Building Network, League of Conservation Voters, Learning Disabilities Association of America, Maryland PIRG, Natural Resources Defense Council, Science and Environmental Health Network, Texas PIRG (TexPIRG), Toxic-Free Future, U.S. PIRG, United Steelworkers, WashPIRG, WE ACT for Environmental Justice, Women for a Healthy Environment

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232	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General
233	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure
234	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Systematic Review
235	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General

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OVERVIEW Through LCSA, Congress amended the Toxic Substances Control Act (TSCA) to establish a new framework for conducting timely, comprehensive and science-based risk evaluations for chemicals of concern. The law provides that EPA's evaluations must be strictly risk-based and must result in a definitive determination of whether the evaluated substance as a whole presents an unreasonable risk of injury to health and the environment across its life cycle, without regard to cost and other non-risk factors. In conducting risk evaluations, EPA must address risks not only to the general population but also to "potentially exposed or susceptible subpopulations," including the elderly, children, pregnant women and workers.

On December 19, 2016, as required by section 6(b)(2)(A) of TSCA, EPA selected 10 chemicals for initial risk evaluations. These precedent-setting evaluations address substances with widespread exposure and known health hazards. How EPA evaluates the risks of these chemicals will be critical to whether the public and policymakers are fully informed about the threats they pose to health and the environment. This in turn will determine whether EPA follows through with effective risk reduction measures under section 6(a) of TSCA that protect at-risk populations. The initial evaluations will also lay the groundwork for overall TSCA implementation and thus determine whether EPA establishes the robust and protective chemical risk management program that LCSA calls for.

Unfortunately, the 2017 scoping documents and more recent problem formulations make it increasingly apparent that the initial 10 evaluations will fall far short of the expectations of Congress and the requirements of the law. Through a combination of questionable exclusions and loopholes, failure to require necessary testing, deviations from accepted scientific methods and refusal to accept previous peer reviewed determinations of risk, the Agency is on a path to produce evaluations that ignore important exposure pathways and at-risk populations, disregard evidence of adverse effects and reach misleading and incomplete conclusions that understate risks and weaken public health protection.

The many shortcomings of the scoping documents and problem formulations are compounded by the June 11 TSCA document for applying "systematic review" methods in the TSCA risk evaluations. As explained in our separate comments on this document, it would require data on the 10 chemicals to be reviewed using an arbitrary set of numerical criteria for study quality that has not been peer reviewed and is in conflict with other systematic review approaches used within EPA and by other federal agencies that have been endorsed by authoritative bodies like the National Academy of Sciences (NAS). Application of the TSCA systematic review document will unjustifiably restrict the body of evidence that informs EPA judgments about risk and hamper the Agency's ability to use the most relevant and meaningful data for decision-making on the 10 chemicals.

Because the 10 risk evaluations are likely to deviate dramatically from the goals of the law and take a large step backward in protecting public health, EPA should put them on hold, rethink how they are being conducted, and reinitiate them in accordance with the law and principles of sound science.

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236	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy
237	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	RegNex
238	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure
239	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure
240	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Exposure

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SUMMARY OF KEY POINTS As described more fully in the body of these comments, we have the following fundamental concerns about the approach to risk evaluation reflected in EPA's scoping documents and problem formulations: • Congress intended the scope of risk evaluations to be defined within six months after their initiation. Problem formulations are not an authorized step in the risk evaluation process and cannot be used to revisit issues of scope after the Agency has issued a scoping document in accordance with section 6(b)(4)(D). The problem formulations on the 10 chemicals are unlawful under TSCA because they go far beyond the scoping documents in excluding uses, exposures and hazards from the risk evaluations. (Section I, page 6)
• In direct contrast to the scoping documents, all the problem formulations provide that EPA will not consider environmental exposure pathways that could be addressed under other laws administered by EPA. This approach would remove all environmental exposure pathways – a significant contributor to human health risk for many chemicals – from the TSCA risk evaluation process. This dramatic narrowing of TSCA's scope is contrary to the plain language of the law and will defeat the central purpose of TSCA reform – to conduct comprehensive risk evaluations on ubiquitous chemicals that examine the impacts on health and the environment of all of the diverse pathways and modes of release that may result in harm. (Section II, pages 7-12)
• In an extension of this approach, several of the problem formulations indicate that EPA will not evaluate the risks of general population exposure to the 10 chemicals. However, if the presence of a chemical in environmental media – and therefore exposure to the chemical by the general population – is attributable to its "conditions of use," there is no basis for excluding this background level of exposure from EPA's risk evaluation. Moreover, EPA cannot perform its obligation under the law to "integrate and assess" information on exposure if it ignores the contribution of general population exposure to the overall risk that a chemical poses to subpopulations that have additional sources of exposure. (Section III, pages 12-13)
• More broadly, neither the scoping documents nor the problem formulations shed any light on how EPA risk evaluations will account for multiple pathways of exposure by the general population or subpopulations. Instead, it appears that EPA will examine each source of exposure in isolation and will not consider either the combined effect of multiple exposures or the contribution of environmental releases to overall exposure and risk. This is a violation of TSCA. (Section IV, pages 13-14)
• Despite the deep concerns of commenters, the problem formulations reaffirm EPA's exclusion from its risk evaluations of ongoing use and disposal of chemical products that are no longer being manufactured (so-called "legacy uses"). This use and disposal clearly falls within the TSCA definition of "conditions of use" and its exclusion violates the plain language of the law. As the case of asbestos illustrates, discontinued products may be ubiquitous in the built environment and their contribution to current and future exposure and risk may greatly dwarf that of the few products that remain in commerce. To ignore this source of risk would deprive the public, scientists and regulators of important information about threats to public health and prevent policymakers from taking meaningful action to protect at-risk populations. (Section V, pages 14-16)

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241	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Exposure
242	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Human Health, Eco Health
243	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Exposure
244	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Exposure, Human Health
245	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	RegNex

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• Further narrowing the scope of risk evaluations, EPA has determined that it will not address recently discontinued uses of chemicals. The goals of TSCA would be defeated if manufacturers of unsafe chemicals could circumvent scrutiny simply by ceasing production for specific uses before EPA completes a risk evaluation of those uses and then later re-entering the marketplace free from any restriction or determination of risk. This scenario is of particular concern where the product phase-out is in response to agency scrutiny and intended to avoid the consequences of an adverse risk finding and subsequent regulatory action. Although EPA claims that discontinued uses are not "conditions of use" as defined in TSCA, the future resumption of these uses can be "reasonably foreseen" and thus would satisfy the statutory definition. By including such uses in its risk evaluation, EPA could then ban or restrict them permanently under section 6(a), providing certainty to the marketplace and long-term public health protection. (Section VI, pages 16-18)
• Our groups have repeatedly called for EPA to identify data gaps that limit its ability to reach definitive conclusions about the health and environmental effects of the 10 chemicals. However, the problem formulations make a minimal effort to identify the absence of data on the 10 chemicals and address how lack of information will impact the conclusions reached in the risk evaluations. In the face of material data gaps, an unqualified conclusion that a chemical does not "present an unreasonable risk of injury" to health could not be defended under TSCA and would misinform the public about the chemical's safety. Thus, EPA should be explicit about the health and environmental end-points that lack adequate data and exclude these end-points from its determinations of unreasonable risk. It should also use its TSCA authorities to require manufacturers to conduct testing to develop adequate data for a defensible risk evaluation so that future assessments can be informed by a comprehensive dataset. (Section VII, pages 18-23)
• The problem formulations indicate that conditions of use that present de minimis risks will not be further analyzed or addressed in risk evaluations. However, EPA has provided no general criteria for determining levels of exposure that are insignificant. Nor has it provided any information to demonstrate that the uses it plans to drop lack meaningful exposure potential, either in themselves or in relation to their contribution to overall exposure. EPA may have some latitude to devote greater effort to some exposure scenarios than others, but this does not excuse ignoring particular conditions of use based on the unsubstantiated claim that their risks are negligible. (Section VIII, pages 23-24)
• As the asbestos risk evaluation illustrates, EPA has also dropped from consideration significant health end-points known to be linked to exposure to the chemical. This omission is likewise contrary to TSCA's comprehensive approach to evaluating risk. (Section IX, pages 24-25)
• Occupational exposure is significant for nearly all of the 10 chemicals and should be a major focus of EPA's risk evaluations. The problem formulations indicate that when evaluating occupational risks, the Agency will heavily weigh applicable workplace standards. Although these standards may be relevant, EPA should not presume that they are fully protective of workers or that their existence can be equated with the absence of unreasonable risk. OSHA and EPA apply differing standards of protection by law; several OSHA standards are obsolete and do not reflect best available science; OSHA standards do not cover all workers with exposure to regulated chemicals; compliance with OSHA standards is uneven and variable; and as EPA has recognized, some of the industrial hygiene strategies embodied in OSHA standards – such as labels and respirators – are known to be of limited effectiveness in protecting workers. EPA should explicitly recognize these considerations in determining whether risks to workers are unreasonable under TSCA. (Section XII, pages 29-32)

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246	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy
247	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy
248	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy

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I. The Problem Formulations Have No Basis in the Law and Improperly Narrow the Scope of the 10 Risk Evaluations Section 6(b)(4)(D) of amended TSCA provides that, "not later than 6 months after the initiation of a risk evaluation," EPA must "publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and the potentially exposed or susceptible subpopulations the Administrator expects to consider." There is no authorization in the law for issuing a "problem formulation" document at a later point in time to further refine, expand or narrow the scope of the risk evaluation. Nor is this step identiifed in EPA's final risk evaluation framework rule issued under TSCA section 6(b)(4)(B).
Nonetheless, when it released its scoping documents for the 10 chemicals in June 2017, EPA announced that it was also developing problem formulations. It justified this step on the basis that it had been unable to process all the information gathered during the scoping process and the scoping documents were not as "refined or specific" as EPA had hoped. Although the problem formulations may have performed a useful role under these unique circumstances, we do not support repeating this step for additional risk evaluations that EPA conducts. The intent of Congress was to provide clear notice to the public of the scope of risk evaluations within six months after they are initiated. This goal will be undermined if EPA retains the discretion to revisit issues of scope throughout the risk evaluation process and to continuously modify the hazards, uses and exposures that its evaluations will address.4 Thus, problem formulation should be a one-time activity, limited to the special case of the first 10 chemicals, and not part of the risk evaluation process in the future. Footnote: 4 Thus, instead of taking comments on proposed scoping documents and addressing them in final scoping documents issued six months after a risk evaluation is initiated, EPA is now requesting comments on scope issues 20 months into the risk evaluation process. EPA plans to release draft risk evaluations by the end of 2018. Thus, it will be unable to review the comments and modify the evaluations without delaying their completion. In practice, this creates a high likelihood that the comments will be ignored. EPA admits as much by acknowledging that it plans to respond to the comments only when the risk evaluations are final.
We are also concerned that the problem formulations on the 10 chemicals go far beyond the scoping documents in excluding uses, exposures and hazards from the risk evaluations. Not only are these exclusions not justified under TSCA5 but they narrow the evaluation significantly after its scope had been established in accordance with section 6(b)(4)(D). Since problem formulation is not a recognized step in the risk evaluation process or a substitute for scoping under LCSA, it cannot be used to narrow a risk evaluation's scope after-the-fact. Thus, the additional exclusions established in the problem formulations are unlawful. Footnote: 5 EPA's final risk evaluation rule, in contrast to its proposal, would permit the Agency to select which conditions of use to address in risk evaluations. 82 Fed. Reg. 33726 (July 20, 2017). SCHF and several of its partner organizations argued in their comments on the proposal that the law requires the Agency to address all conditions of use in its evaluations. Along with several other groups, SCHF is challenging EPA's contrary interpretation in its petition for judicial review of the risk evaluation rule. Safer Chemicals Healthy Families v. EPA, 17-72260 (9th Cir.) Regardless of the outcome of this challenge, we believe that EPA has no basis to narrow the risk evaluation to exclude conditions of use once they have been included in its scope.

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249	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	RegNex, Exposure
250	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Policy, Exposure

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II. EPA's Extreme Approach of Removing All Environmental Exposure Pathways from Risk Evaluations Is Contrary to the Plain Language and Structure of TSCA and Will Defeat the Central Purpose of TSCA Reform

In direct contrast to the scoping documents, all 10 of the problem formulations provide that EPA will not evaluate the risks of "exposure pathways that are under the jurisdiction of regulatory programs and associated analytical processes carried out under other EPA-administered environmental statutes – namely, the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA), and the Resource Conservation and Recovery Act (RCRA)."6 EPA's rationale for this blanket exclusion is that it "believes that certain programs under other Federal environmental laws adequately assess and effectively manage the risks for the covered exposure pathways." As the Agency explains, "[t]he provisions of various EPA-administered environmental statutes and their implementing regulations represent the judgment of Congress and the Administrator, respectively, as to the degree of health and environmental risk reduction that is sufficient under the various environmental statutes."

Since the laws cited by EPA potentially apply to all releases into the environment, the effect of EPA's approach would be to remove environmental exposure pathways in their entirety from the TSCA risk evaluation process. This extreme approach is without any basis in the text of the law and will defeat the central purpose of TSCA reform – to conduct comprehensive risk evaluations on ubiquitous chemicals that examine the impacts on health and the environment of all of the diverse pathways and modes of release that may result in harm. Environmental media – air, surface water, groundwater, drinking water and waste – are known and pervasive sources of exposure for many substances. Any risk evaluation that fails to account for their contribution to total exposure will provide the public with a misleading and incomplete account of their potential to harm human health and fail to identify critical opportunities for risk reduction.

A. TSCA Risk Evaluations Must Examine Total Risk and Consider All Contributors to Exposure and Conditions of Use

Risk evaluations under TSCA section 6(b)(4)(A) must determine "whether a chemical substance presents an unreasonable risk of injury to health or the environment." These evaluations must therefore examine the totality of risks presented by the substance, taking into account all contributors to exposure, including not just its presence in the workplace or consumer products but its releases into the environment. Indeed, under the plain language of the statute, EPA's focus expressly includes risks to the environment in addition to human health. "Environment" is defined in section 3(6) to include "air, water and land and the interrelationship which exists among and between air, water and land and all living things." If EPA excludes the chemical's presence in environmental media (air, water and soil) and the impacts on the environment of that presence on humans and other living things, then it cannot meet its obligation to determine environmental risks.

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251	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Policy, Exposure
252	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy, Exposure

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Section 6(b)(4)(A) also provides that a risk evaluation must also determine the substance's risks under "the conditions of use." This broad term spans the entire life cycle of a chemical. It is defined under section 3(4) to mean "the circumstances . . . under which a chemical substance is intended, known or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of." The "circumstances" to which the definition applies clearly include air emissions and water discharges from industrial facilities as well as releases to environmental media during disposal. For EPA to exclude all such environmental releases from its risk evaluations would remove from the application of the law a large category of "conditions of use" that Congress directed EPA to address.7 Footnote: 7 As SCHF and its co-petitioners have argued in their brief in Safer Chemicals Healthy Families v. EPA, the statute gives EPA no discretion to exclude any conditions of use from risk evaluations, let alone the broad universe of environmental releases that occur during manufacture, processing, use, distribution in commerce and disposal of a chemical substance.
B. Environmental Exposure Pathways Are Central to Chemical Prioritization, Risk Evaluation and Regulation under Section 6 of TSCA Other provisions in section 6 confirm the need to consider environmental releases as part of chemical prioritization and risk evaluation. For example, storage near significant sources of drinking water is a factor that EPA must examine in its process for designating chemicals as high- or low-priority under section 6(b)(1)(A). Similarly, under both this provision and section 6(b)(2)(D), chemicals with significant potential for persistence, bioaccumulation and toxicity (PBTs) must receive preference in the selection of substances for high-priority listing. PBTs are of concern because of their presence in environmental media and potential to concentrate in animals and humans as they are distributed in air, water and soil taken up the food chain. If EPA does not consider environmental release pathways of PBTs in evaluating their risks, it would be pointless to designate them as high-priority since the ensuing evaluation could not meaningfully address the contribution of environmental exposure pathways to total risk.

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253	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy, Exposure
254	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy

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Paralleling the expansive definition of "conditions of use," the regulatory authorities in section 6(a) of the law empower EPA to take a broad array of actions to restrict chemical exposures and releases in order to eliminate unreasonable risks to health and the environment. Under the original law, EPA in fact used section 6(a) on a number of occasions to curtail environmental releases of toxic chemicals.8 Indeed, section 6(a)(6)(A) authorizes EPA to impose a "requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes." The authority to regulate disposal (a broad concept that can include virtually any release of wastes into air, water or land) would be meaningless if EPA did not use risk evaluations under section 6(b) to identify disposal activities that present an unreasonable risk of injury and are subject to restriction under section 6(a). Footnote: 8 Of the 6 existing chemicals EPA regulated under section 6 under the original law, the prevention of environmental releases was the basis for three of these regulatory actions. In 1978, EPA banned nonessential uses of fully halogenated chlorofluoroalkanes as propellants in aerosol spray containers because of concerns that these chemicals were destroying the upper atmosphere's ozone layer. In 1980, EPA promulgated a rule prohibiting Vertac Chemical Company and others from removing for disposal certain wastes containing 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) stored at Vertac's Jacksonville, Arkansas, facility. The rule also required any persons planning to dispose of TCCD contaminated wastes to notify EPA 60 days before their intended disposal. In 1994, EPA promulgated a rule to eliminate emissions of hexavalent chromium from comfort cooling towers.
C. TSCA Legislative History Demonstrates that the Law Was Intended to Address Environmental Releases that May Be Within the Purview of Other Laws If Congress had intended a blanket exemption for environmental releases from risk evaluations under section 6(b) and regulation under section 6(a), it surely would have said so explicitly given the farreaching impact of such an exemption. Not only is there no such exemption in the law, but its legislative history and structure demonstrate that Congress intended TSCA to provide a comprehensive framework for identifying and managing chemical risks, including those that derive from environmental exposure pathways and could be addressed under other environmental laws.

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255	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy
256	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy

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The comprehensive scope of TSCA was underscored in the legislative history of the original law. Congress recognized that then-existing environmental laws were "clearly inadequate" to address the "serious risks of harm" to public health from toxic chemicals. H.R. Rep. No. 94-1341, at 7 (1976); see S. Rep. No. 94-698, at 3 ("[W]e have become literally surrounded by a manmade chemical environment. ... [T]oo frequently, we have discovered that certain of these chemicals present lethal health and environmental dangers."). While other federal environmental laws focused on specific media, such as air or water, none gave EPA authority to "look comprehensively" at the hazards of a chemical "in total." S. Rep. No. 94-698, at 2. Congress designed TSCA to fill these "regulatory gaps," S. Rep. No. 94-698, at 1, through a comprehensive approach to chemical risk management that considered "the full extent of human or environmental exposure," H.R. Rep. No. 94-1341, at 6.

In amending TSCA in 2016, Congress sought to promote "effective implementation" of the 1976 law's objectives. See S. Rep. No. 114-67, 114th Cong., 1st Sess. (2015) at 2. At the time it strengthened TSCA, Congress affirmed that the intent of the original law—to give EPA "authority to look at the hazards [of chemicals] in total," S. Rep. No. 94-698, at 2—remained "intact." S. Rep. No. 114-67, at 7. Indeed, in a statement accompanying the law's passage, its Senate Democratic sponsors underscored that, with the expanded authorities conferred by Congress, TSCA should not be "construed as a 'gap filler' statutory authority of last resort" but "as the primary statute for the regulation of toxic substances." Excluding all pathways of chemical exposure through air, water and soil from risk evaluations would be directly contrary to these Congressional expectations.

D. TSCA Section 9(b) Provides that EPA Must Decide Whether TSCA or Another Law is the Best Vehicle for Risk Management Only After Evaluating the Risks of a Chemical's Environmental Releases under TSCA

In the 1976 law, Congress recognized the need to coordinate use of TSCA with implementation of other environmental laws. However, it chose to do so not by excluding environmental releases from the purview of TSCA – the approach EPA is pursuing now. Instead, it established a framework for determining, on a case-by-case basis, whether the risks of particular chemicals are best addressed under these laws or under TSCA. Thus, section 9(b)(1) of TSCA provides that EPA may use TSCA regulatory authorities if it "determines, in [its] discretion, that it is in the public interest to protect against [a particular] risk by action taken under this Act" but should use other environmental laws if it determines that "a risk to health or the environment . . . could be reduced to a sufficient extent by actions taken under" these laws.

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257	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy
258	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy
259	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Policy

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In 2016, Congress underscored the chemical-specific focus of this analysis by revising section 9(b)(2) so that, in deciding whether to regulate under TSCA or another law, EPA must "consider . . . all relevant aspects of the risk" in question and make a "comparison of the estimated costs and efficiencies" of addressing the risk under TSCA and other laws. Commenting on this language, the law's Senate Democratic sponsors explained that it allowed EPA to regulate under other laws in lieu of TSCA only where the "Administrator has already determined that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by additional actions taken under other EPA authorities." This approach presupposes that EPA has already used the TSCA risk evaluation process to identify the risks of a chemical and the exposure pathways contributing to those risks and thus has an informed basis to determine whether they "could be eliminated or reduced to a sufficient extent" under another law. If EPA has not examined the specific pathways of environmental exposure and their contribution to total risk under TSCA, then it cannot conduct the analysis that section 9(b) requires because it will be unable to evaluate the relative strengths of using TSCA or another law to eliminate the risk. By presuming that other laws are always superior to TSCA in identifying and reducing the risks of chemicals in environmental media, EPA's blanket exclusion of environmental releases thus turns section 9(b) on its head.
E. Contrary to EPA, There is No Basis to Conclude that Other Environmental Laws are Equivalent in Scope and Protectiveness to TSCA EPA's position that other environmental laws should displace TSCA risk evaluations for all chemicals arbitrarily assumes that these laws provide equivalent protection of public health and the environment and that there is no added benefit in addressing environmental pathways of exposure under TSCA. But in reality these other laws vary greatly in the degree of protection they afford against chemical risks and the extent of their application to unsafe chemicals. These limitations are precisely why Congress gave EPA comprehensive authority over chemical risks under TSCA in 1976 and strengthened that authority in 2016.
The 2016 TSCA amendments establish a risk-basic framework for EPA's decisions on chemical safety and set a high standard of protection of health and the environment. Under section 6(b)(4)(A), TSCA risk evaluations must: "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors" (emphasis added). This determination must be for both the general population and "potentially exposed or susceptible subpopulations." Once an unreasonable risk is identified, TSCA section 6(c)(1) requires EPA to issue a rule under section 6(a) to address the risk. Section 6(a), in turn, directs that this rule must restrict the chemical "to the extent necessary so that the chemical substance no longer presents such risk" – again assuring protection of potentially exposed or susceptible subpopulations. As EPA has recognized, it cannot lower this level of protection based on consideration of costs and benefits. Although the rule must be accompanied by an economic analysis, the restrictions it imposes must be sufficient to eliminate the unreasonable risk identified in the evaluation. Indeed, the 2016 TSCA revisions were explicitly designed to remove the cost-benefit framework required under the old law because it had impeded meaningful regulation of unsafe chemicals.

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260	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Policy
261	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Policy
262	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Policy

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TSCA's strict risk-based framework for chemical risk management is not mirrored in most environmental laws that govern releases to air, water and soil and disposal of waste. For example, the standard-setting process to establish discharge limits for chemical and other pollutants under the Clean Water Act (CWA) is technology-based and does not allow for consideration of risk. The same is true of several provisions of the Clean Air Act (CAA) that regulate emissions from new and modified stationary sources of pollution and mobile sources. In addition, the primary CAA mechanism for controlling industrial emissions of air toxics calls for EPA to set standards requiring Maximum Achievable Control Technology (MACT), an approach that does not take into account risks to health, although any "residual risks" can be addressed in a second stage of rulemaking.
Even statutes that do allow for consideration of risks also direct EPA to weigh cost and other economic factors. The Safe Drinking Water Act (SDWA), for example, requires cost-benefit balancing in setting limits for drinking water contaminants, the very approach rejected in the 2016 TSCA amendments. The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), which governs the remediation of contaminated sites, focuses on health protection but also directs EPA to take into account costs and technical achievability.17 And importantly, most of these laws do not include TSCA's explicit protections for potentially exposed or susceptible subpopulations at higher risk than the general population. In short, the bulk of EPA-implemented environmental laws lack the high level of protectiveness and exclusive focus on eliminating unreasonable risks that Congress demanded in its recent TSCA revisions.
Equally important, in comparison to TSCA, the scope of regulation under other federal environmental laws is limited: these laws generally apply to only a subset of the substances that may present risks to health or the environment and only a subset of the facilities whose environmental releases contribute to these risks. For example, air toxics emission requirements in the CAA only address 189 Hazardous Air Pollutants (HAPs) designated by Congress in the 1990 CAA amendments and only large industrial emitters that meet the CAA definition of "major source" are subject to emission limits. Similarly, CERCLA cleanups encompass a statutory list of hazardous substances and disposal requirements under the Resource Recovery and Conservation Act (RCRA) only apply to those wastes that EPA has designated as "hazardous." Industrial discharge limits under the CWA only apply to regulated "toxic" pollutants and the CWA's water quality framework involves a complex mix of state and federal standards that vary across regions, may not address all pollutants that threaten human health and often do not result in uniform levels of protection. These basic gaps in coverage are painfully evident as EPA and states struggle to address widespread contamination and threats of harm to human health resulting from the extensive use and environmental release of Per- and polyfluoroalkyl substances (PFAS). Despite their significant risks, PFAS chemicals are not regulated as HAPs under the CAA, drinking water contaminants under the SDWA, hazardous substances under CERCLA or toxic pollutants under the CWA.

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Y
Y

263	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy
264	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy
265	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure
266	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Exposure
267	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Exposure

N/A
N/A
2.6
N/A
N/A

While EPA may have authority to expand the reach of its environmental laws to include previously unregulated toxics, it cannot do so without first evaluating the risks of these chemicals. With limited exceptions, however, EPA has no obligation under its environmental laws to assess the risks of unregulated chemicals or even to update its understanding of the hazard and exposure profile of those substances that are regulated. In practice, moreover, EPA's other regulatory programs have limited resources and many competing priorities, including those required by specific statutory provisions and/or court orders. Thus, there is little likelihood that previously unaddressed chemical risks will be evaluated by these programs. Indeed, many existing environmental standards are decades old and no longer reflect the best available science but EPA's environmental media programs lack the bandwidth and inclination to update them based on current understanding of risks to human health and the environment. For all these reasons, by precluding the use of TSCA to determine the health and environmental impacts of chemical releases to air, water and soil, EPA is effectively closing the door to any meaningful evaluation of these impacts – and, thus, to the use of TSCA or other laws to restrict those releases that are found to be unsafe.
In sum, exclusion of all environmental releases from TSCA risk evaluations is contrary to the wording, intent and purposes of the law and will inevitably mean that serious threats to health and the environmental are neither identified nor addressed.
III. There is No Legal or Technical Justification for Excluding General Population Exposure from EPA's Risk Evaluations Several of the problem formulations indicate that EPA will not evaluate the risks of general population exposure. As stated in the PERC problem formulation: EPA does not plan to consider and analyze general population exposures in the risk evaluation for PERC. EPA has determined that the existing regulatory programs and associated analytical processes have addressed or are in the process of addressing potential risks of TCE that may be present in various media pathways (e.g., air, water, land) for the general population. For these cases, EPA believes that the TSCA risk evaluation should focus not on those exposure pathways, but rather on exposure pathways associated with TSCA uses that are not subject to those regulatory processes.
This approach is unjustified for the reasons discussed above. If the presence of a chemical in environmental media – and therefore exposure to the chemical by the general population – is attributable to its "conditions of use", there is no basis for excluding this background level of exposure from EPA's risk evaluation. The claim that this exclusion is justified because "existing regulatory" programs apply to environmental releases is unsupported by the law: in accordance with section 9(b), EPA must first determine the risk resulting from environmental releases through a TSCA risk evaluation and then determine whether the risk is best addressed under TSCA or other EPA-administered environmental laws.
The goal of risk evaluations under section 6(b)(4)(A) is to determine the risks presented by a chemical as a whole, not the risks of individual uses and pathways in isolation. Moreover, section 6(b)(4)(F) directs EPA to take into account "the likely duration, intensity, frequency and number of exposures under the conditions of use of the chemical substance" and to "integrate and assess available information on hazards and exposures for the conditions of use." This integrating analysis cannot be performed if some pathways of exposure are excluded simply because they involve environmental media and could be subject to other laws. As the House Report for original TSCA emphasized, "[i]ntelligent standards for regulating exposures to a chemical in the workplace, the home or elsewhere in the environment cannot be set unless the full extent of human or environmental exposure is considered."

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268	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure
269	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, PESS, Exposure
270	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure, PESS
271	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure

N/A
N/A
N/A
Executive Summary

The background levels of a chemical in the environment may present an unreasonable risk to the general population in their own right or they may add to other sources of exposure to present an overall risk to specific populations that is unreasonable. In either event, EPA cannot discharge its obligations under the law unless it determines and takes into account the background levels of a chemical to which the general population is exposed.
IV. EPA's Continues to Fail to Explain What Methodology It Will Use to Account for Multiple Exposure Pathways that Increase Overall Risk The law's clear requirements for evaluating and protecting against risks to "potentially exposed or susceptible subpopulations" further underscore EPA's obligation to consider all contributors to exposure and risk, including a chemical's presence in environmental media. In order to determine whether a subpopulation may be at greater risk because it has greater exposure than the general population, the Agency must first quantify general population exposure and then determine how this exposure is increased because of exposures in the workplace, through products, as a result of environmental releases or because of other pathways that affect a particular subpopulation. To protect these subpopulations, EPA's focus must be on whether the total risk they face, considering all sources of exposure, is unreasonable. If one or more contributors to exposure are ignored, groups who are at greater risk than the general population because of multiple exposure pathways will be inadequately protected.
Recognizing the need to account for the impact of multiple sources of exposure, TSCA section 6(b)(4)(F)(ii) requires risk evaluations to describe whether aggregate or sentinel exposures to a chemical were considered and the basis for that consideration. To properly apply either or both of these approaches in a risk evaluation, EPA must determine in advance what methodology it will employ and then incorporate it in the risk evaluation design in sufficient detail to describe the key data sources it will use to assess exposure and how they will be used. EPA has not done this. Disappointingly, neither the scoping documents nor the problem formulations shed any light on how EPA risk evaluations will account for multiple pathways of exposure by the general population or subpopulations. Instead, it appears that EPA will examine each source of exposure in isolation and will not consider either the combined effect of multiple exposures or the contribution of environmental releases to overall exposure and risk. This is a violation of TSCA.
V. Ongoing Use and Disposal of Chemical Products that are No Longer Being Manufactured Fall Within the TSCA Definition of "Conditions of Use" and Cannot Be Excluded from Risk Evaluations Among the 10 chemicals are substances, such as asbestos and HBCD, that contribute to ongoing exposure and risk as a result of historical manufacturing and processing activities that have been discontinued. In many cases, the current and foreseeable risks associated with these activities are significant. Nonetheless, the problem formulations, like the scoping documents, take the position that they are outside the scope of risk evaluations. As stated in EPA'S asbestos problem formulation: "In the case of asbestos, legacy uses, associated disposals, and legacy disposals will be excluded from the problem formulation and risk evaluation, as they were in the Scope document. These include asbestos containing materials that remain in older buildings or are part of older products but for which manufacture, processing and distribution in commerce are not currently intended, known or reasonably foreseen. EPA is excluding these activities because EPA generally interprets the mandates under section TSCA § 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacture, processing or distribution is intended, known to be occurring, or reasonably foreseen, rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of conditions of use in that context."

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Y
Y

272	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy
273	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure
274	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy, Exposure
275	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure
276	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy

2.2
2.2, 2.3
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2.2

EPA is incorrectly interpreting the provisions of LCSA. The definition of "conditions of use" in section 3(4) includes the "circumstances . . . under which a chemical substance is . . . known or reasonably foreseen to be . . . used or disposed of." Where a chemical is performing an ongoing in situ function as a result of previous manufacturing and processing activity, that function comprises a current "use" of the chemical that is "known" to be occurring.26 Footnote: 26 SCHF and its co-petitioners are challenging EPA's position that ongoing use and disposal of discontinued products are not TSCA "conditions of use" in Safer Chemicals Healthy Families v. EPA, 17-72260 (9th Cir.) In addition to being used and disposed of, legacy products that perform functions in the built environment can be considered "distributed in commerce" as this term is defined in TSCA section 3(5). The definition includes "to hold, or the holding of, the substance, mixture or article after its introduction in commerce" – language that plainly applies to in situ products. Likewise, the definition includes the "introduction or delivery for introduction into commerce" of the substance, mixture or article. This description would apply to legacy products that are repurposed or sold for recycling.
To exclude from risk evaluations ongoing and future exposures from in situ uses of discontinued products would create a sizable gap in the life-cycle assessments of risk that Congress directed EPA to conduct under the new law. This would deprive the public, scientists and regulators of a comprehensive picture of one of the largest sources of continuing and future risk. Since in situ sources of exposure form a critical component of the background levels of asbestos and other chemicals to which the general population is exposed, EPA's assessment of risks to particular subpopulations from more specific exposure pathways would also be incomplete and understated.
In addition, decision-makers would be unable to reduce ongoing exposures and impose safeguards against unsafe use and disposal and "legacy" products because they would lack a meaningful risk evaluation to inform these actions. Just as TSCA provides authority to evaluate the risks associated with ongoing exposures from discontinued activities, so it gives EPA the authority under section 6(a) to reduce these risks, yet the Agency would be stymied by the absence of a risk evaluation that provides a basis for such regulation.31 Footnote: 31 For some chemicals like lead and asbestos, other laws administered by EPA address handling and disposal of in situ materials and the Agency may be able to refer the findings of its risk evaluations to the programs implementing these laws under TSCA section 9(b) in lieu of further regulation under section 6. However, there are no existing laws that address ongoing exposure from use and disposal of discontinued products containing HBCD, perfluorinated chemicals and other substances and therefore the availability of the protections afforded under section 6 of TSCA may be critical to addressing their risks. Obviously, if these risks are not identified and evaluated under TSCA section 6(b), there will be no basis for reduction them through regulation under section 6(a).
In short, EPA must characterize and assess ongoing exposures from the use and disposal of discontinued products and determine the risks they present as part of its risk evaluations on the initial 10 chemicals. Its continuing failure to do so is a clear violation of TSCA.
VI. Uses Discontinued under the Threat of Regulatory Action Fall Within the TSCA Definition of "Conditions or Use" and Must be Addressed in TSCA Risk Evaluations A number of the problem formulations indicate that certain chemical uses have been discontinued and therefore will not be addressed in the risk evaluation for that chemical.

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278	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy
279	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy
280	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy

2.2
N/A
N/A

We disagree with EPA that discontinuance of a previously widespread use necessarily places it beyond the reach of section 6 risk evaluation and management authorities. EPA provides no justification for its assertion that the TSCA definition of "conditions of use" does not apply to such uses. As defined in section 3(4), this term includes not simply intended or known uses but the "circumstances under which a chemical substance is . . . reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of." It is clearly "reasonably foreseen" that long-standing and significant uses of a chemical that have been phased out may re-enter commerce in the absence of any legal restriction. Moreover, section 6(a) provides that EPA must regulate a chemical where "manufacture, processing, distribution in commerce, use or disposal" presents an unreasonable risk but does not stipulate that these activities must be currently occurring to warrant restriction. Indeed, the purpose of section 6(a) rules – to impose the measures "necessary so that the chemical substance no longer presents [an unreasonable] risk" – is equally applicable to ongoing commercial activities and to historical uses that could resume and require restrictions so they do not cause harm to health and the environment.
Although the 2016 TSCA amendments removed the phrase "will present" from section 6(a), the statement of Democratic sponsors at the time of enactment makes clear that EPA retained its authority to address anticipated future risks: "Existing TSCA as in effect before the date of enactment of Frank R Lautenberg Chemical Safety for the 21st Century Act includes the authority, contained in several sections (see, for example, section 6(a)), for EPA to take regulatory actions related to chemical substances or mixtures if it determines that the chemical substance or mixture 'presents or will present' an unreasonable risk to health or the environment. The Frank R. Lautenberg Chemical Safety for the 21st Century Act includes language that removes all instances of 'will present' from existing TSCA and the amendments thereto. This does not reflect an intent on the part of Congressional negotiators to remove EPA's authority to consider future or reasonably anticipated risks in evaluating whether a chemical substance or mixture presents an unreasonable risk to health or the environment. In fact, a new definition added to TSCA explicitly provides such authority and a mandate for EPA to consider conditions of use that are not currently known or intended but can be anticipated to occur . . . "
The goals of TSCA would be defeated if manufacturers of unsafe chemicals could avoid scrutiny simply by ceasing production for specific uses before EPA completes a risk evaluation of those uses and then later re-entering the marketplace free from any restriction or determination of risk. This scenario is particularly troubling where the product phase-out is in response to agency risk concerns and intended to avoid the consequences of an adverse risk finding and subsequent regulatory action. In these cases, the best interpretation of TSCA is to treat the possible reintroduction of a discontinued use as "reasonably anticipated," to address that use in the risk evaluation and to then ban or restrict it permanently under section 6(a) if it is determined to present an unreasonable risk.

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281	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy
282	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy
283	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy

N/A
N/A
N/A

We do not believe a SNUR is an adequate substitute for evaluation and regulation of a discontinued chemical use under section 6. SNURs are fundamentally notification requirements and do not themselves require an assessment or determination of risk. The activities they define as "significant new uses" are not prohibited: companies seeking to conduct these activities must notify EPA at least 90 days before initiating them. While the Agency must review the new use and ban or restrict it under sections 5(e) or 5(f) upon determining that the use does or may present an unreasonable risk, the Agency may or may not choose to take these actions. Thus, the door will not be closed to reintroduction of the use. Moreover, EPA's review of a SNUN and decision to regulate the new use lack the elements of openness and accountability that apply during section 6 risk evaluations and rulemakings. Thus, these decisions will receive limited public and judicial review.

A comprehensive risk evaluation under section 6, by contrast, enables the Agency to make a definitive risk determination for plausible future risk scenarios in a transparent process that provides clarity to industry and the public and closes the door to the resumption of unsafe uses. If there is a role for a SNUR, it is to perform the limited stop-gap function of assuring that EPA is notified of significant changes in use while its risk evaluation and follow-up rulemaking are underway so that these uses are not reestablished in the marketplace before EPA has addressed their risks under section 6 and restricted them if warranted.

VII. EPA Should Not Make Determinations of Unreasonable Risk for Endpoints that Lack Adequate Information and Should Use its Section 4 Authorities to Require Industry to Fill These Data gaps

Our groups have repeatedly called for EPA to identify data gaps that limit its ability to reach definitive conclusions about the health and environmental effects of the 10 chemicals. We have urged EPA to take steps to fill these data gaps early in the risk evaluation process using its expanded TSCA information development authorities so that sufficient information is available for an informed evaluation. EPA itself has emphasized the need for comprehensive data on hazard and exposure before it initiates evaluations although it has backed away from a systematic information collection process at the pre-prioritization stage for risk evaluation candidates.36 Basing risk evaluations on adequate data is not only necessary to meet EPA's obligation under section 26(k) to consider all "reasonably available information" but furthers section 2(b)(2), which declares that "[i]t is the policy of the United States" that "adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment."

Footnote:

36 In the discussion paper EPA prepared for its December 11, 2017 public meeting on prioritization, EPA stated that: Prior to designating a chemical as a high-priority for risk evaluation, it is important for EPA to ensure the reasonably available information is sufficient to conduct a scientifically robust risk evaluation. In many cases, EPA believes it would be difficult to require the development of necessary chemical substance information, evaluate that information, and incorporate that information into analyses and decisions within the statutory timeframes associated with the prioritization and risk evaluation processes. Therefore, it will be useful for EPA to identify information needs and determine whether any of these needs should be addressed before initiating the prioritization process. DISCUSSION DOCUMENT: Possible Approaches and Tools for identifying Possible Candidate Chemicals for Prioritization at 7. Despite this recognition, EPA's final prioritization framework rule deleted a pre-prioritization process that would have expressly provided a process for identifying and filling data gaps before risk evaluations are initiated. Procedures for Prioritization of Chemicals for Risk Evaluation under the Toxic Substances Control Act. 82 Fed. Reg. 33753 (July 20, 2017).

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284	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy
285	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Policy, Human Health
286	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy

N/A
2.4.2
1

It is therefore disappointing that the problem formulations, like the earlier scoping documents, make minimal efforts to identify significant data gaps for the 10 chemicals, to set in motion development of additional information, and to address how these data gaps will impact the conclusions reached in the risk evaluations. Indeed, EPA seems ready to find that substances do not present an unreasonable risk of injury even where available data are lacking entirely or are insufficient under Agency guidelines to determine that a substance lacks adverse effects.37 Footnote: 37 The EPA responses to comments on the scoping documents indicate that: "when OPPT does find existing data are not adequate, OPPT will use all available authorities to fill data gaps necessary to conduct fit-for-purpose assessments." This is not, however, the approach reflected in the problem formulations.
In the face of material data gaps, an unqualified conclusion that a chemical does not "present an unreasonable risk of injury" to health could not be defended under TSCA and would misinform the public about the chemical's safety.51 Thus, EPA's risk evaluations should be explicit about the health and environmental end-points that lack adequate data and should exclude these end-points from its determinations of unreasonable risk. It should also use its TSCA authorities to require manufacturers to conduct testing to develop adequate data for a defensible risk evaluation so that future assessments can be informed by a comprehensive dataset. EPA's lack of interest in using section 4 of the law to generate data necessary for risk evaluation is deeply troubling in light of the clear intent of the 2016 TSCA amendment to provide the Agency with the tools to require more testing by industry to support priority setting and risk evaluations under section 6. Footnote: 51 EPA has recognized that "OPPT does not believe that absence of data equals no risk." EPA's Responses to Public Comments Received on the Scope Documents for the First Ten Chemicals for Risk Evaluation under TSCA (May 2018) at 13. However, the problem formulations suggest that the Agency is not applying this principle in its evaluations of individual chemicals.
VIII. Where EPA Believes that Particular Conditions of Use Present De Minimis Risks, It Cannot Drop These Uses with no Additional Analysis, But Rather Must Explain and Document Why Their Risks Are Insignificant The problem formulations also indicate that EPA "expects to be able to reach conclusions about particular conditions of use, hazards or exposure pathways without further analysis" and will not further address them in its risk evaluations.52 For example, EPA indicates that it will devote no further attention to multiple uses of carbon tetrachloride (CTC) that it asserts pose only de minimis risks: • Because industrial, commercial, and consumer use of such products (solvents for cleaning/degreasing, adhesives/sealants, and paints/coatings) would present only de minimis exposure or otherwise insignificant risk, EPA has determined that these conditions of use do not warrant evaluation, and EPA does not expect to consider or evaluate these conditions of use or associated hazards or exposures in the risk evaluation for carbon tetrachloride. Footnote: 52 This statement apears in the Introduction to all of the Problem Formulations.

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287	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy
288	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy
289	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Human Health

2.2, 2.4.2
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N/A, 2.4.2

Nowhere has EPA provided general criteria for determining levels of exposure or risk that are "insignificant" for purposes of TSCA risk evaluations. Nor has the Agency explained why it considers carbon tetrachloride-containing solvents with potential consumer, industrial and commercial exposure to be so inconsequential that they can be determined not to present "unreasonable risks" without any product-specific analysis of use and release scenarios.54 Since carbon tetrachloride is a carcinogen, even low concentrations cannot be assumed to be safe without some understanding of the conditions and levels of exposure. Moreover, even if the risk from a specific product is small in itself, multiple products and exposure pathways may result in aggregate levels of exposure that present significant risks to one or more worker or consumer subpopulations. As noted above, TSCA requires EPA to examine chemical risks holistically, taking into account all uses and pathways of exposure, and cannot summarily eliminate an entire class of products from consideration. EPA may have some latitude to devote greater effort to some exposure and risk scenarios than others, but this does not excuse ignoring particular conditions of use based on the unsubstantiated claim that they present de minimis risks.

Footnote:

54 EPA's initial use summary found products with up to 2.5% CTC and SCHF's submission to EPA of publically available product information included products with 1% CTC. See Safer Chemicals, Healthy Families, Environmental Health Strategy Center, Healthy Building Network, Comments to the U.S. Environmental Protection Agency (EPA) on the Scope of its Risk Evaluation for the TSCA Work Plan Chemical: CARBON TETRACHLORIDE (CTC) CAS Reg. No. 56-23-5 (March 15, 2017). This information is not reflected in the problem formulation for CTC.

It is also troubling that, despite numerous critical comments, EPA continues to ignore the presence of 1,4-dioxane as an impurity in products on the ground that "contamination of industrial, commercial and consumer products are not intended conditions of use for 1,4-dioxane and will not be evaluated." EPA's position is legally unsupportable. Production of a chemical as a byproduct or impurity is plainly a "circumstance . . . under which a chemical substance . . . is known . . . to be manufactured" and thus falls squarely within the definition of "conditions of use" in section 3(4) of TSCA. There is no basis in this provision or other parts of the law for differentiating between manufacture as a byproduct/impurity and purposeful production and including the latter in a risk evaluation but excluding the former. In the case of 1,4-dioxane, EPA has made no effort to argue that byproduct/impurity production poses de minimis risks and such a position could not be defended given the evidence that 1,4-dioxane's detection in drinking water and groundwater is linked in part to its presence as a contaminant in products and waste streams released into the environment. Plainly, EPA must add 1,4-dioxane production as a byproduct and impurity to the scope of its risk evaluation.

The comprehensive approach to risk evaluations in TSCA requires EPA to address all known hazards of a chemical, particularly one whose dangers to human health are so serious and well documented. The law provides no basis for failing to evaluate documented adverse health effects, let alone effects of this severity and magnitude.

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290	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy
300	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy
301	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy

N/A
N/A
N/A

X. EPA Should Not Revisit Definitive Findings in IRIS Assessments Unless There Are New Data That Inform EPA's Evaluation of the Weight of the Evidence Six of the 10 chemicals -- asbestos, TCE, MC, CTC, PERC and 1,4-dioxane -- have been assessed under the EPA Integrated Risk Information System (IRIS). The IRIS process is the Agency's authoritative mechanism for reviewing available studies, characterizing the health effects of chemicals and identifying concentrations below which these chemicals are not likely to cause adverse effects. IRIS assessments typically reflect years of work by EPA scientists, multiple rounds of public comment, inter and intraagency consultation, and extensive peer review, often by the Agency's independent Science Advisory Board (SAB) or the National Academy of Sciences (NAS). The IRIS program recently received a favorable review from the NAS.
Where EPA is conducting a TSCA risk evaluation of a chemical that has already been assessed under IRIS, the conclusions of the IRIS assessment should be presumed to be applicable to the TSCA evaluation as a definitive statement by the Agency of the best available science. Reopening IRIS findings would harm the public by prolonging uncertainty on issues that have been addressed and resolved through an authoritative, transparent and inclusive EPA process. Like other Agency actions, IRIS assessments often give rise to differences of opinion and some stakeholders may be disappointed by the outcome. But this does not mean that EPA should reinvent the wheel and provide another bite at the apple on scientific determinations that have been made after thorough deliberation. To revisit IRIS findings would also be inefficient and resource-intensive at a time when the Agency is struggling with workforce and budget constraints and is straining to manage its TSCA workload.
The only rationale for revisiting IRIS findings is where significant new data have become available since the final IRIS assessment that could inform the weight of the evidence on particular end-points. If that is the case, then the IRIS program should be tasked with updating its previous assessment, using a systematic review protocol that is consistent with the state of the science such as the National Toxicology Program (NTP) method. In its response to comments on the scoping documents, EPA seems to adopt this limited approach to reopening IRIS conclusions, stating that: "OPPT has used IRIS documents as a starting point for identifying key and supporting toxicity studies and initial hazard identification. However, EPA also expects to consider other available hazard and exposure data to ensure that all reasonably available information is taken into consideration. Specifically, EPA will screen information developed after the completion of any IRIS assessment and evaluate the relevant information using OPPT's structured process . . . "

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Y
Y

302	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy, Systematic Review
303	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy

N/A
N/A

In the problem formulations themselves, however, EPA outlines a much broader approach. It indicates that all studies on IRIS-assessed chemicals will be reviewed using the "study quality" scoring system in EPA's TSCA systematic review document and other as-yet unidentified protocols for reviewing study relevance and weight.61 This process would necessarily involve revisiting the interpretation of studies already evaluated in IRIS, potentially making different judgments about their quality and relevance and modifying overall IRIS determinations of the "best available science" and "weight of the evidence." Moreover, these judgments would be driven by a deeply flawed and unscientific method for reviewing studies that would result in less defensible conclusions than peer reviewed IRIS assessments. Footnote: 61 Typical is this description of EPA's approach in the problem formulation for asbestos, the subject of a comprehensive IRIS assessment: EPA expects to consider and analyze human health hazards as follows: 1) Included human health studies will be reviewed using the evaluation strategies laid out in the Application of Systematic Review in TSCA Risk Evaluations (U.S. EPA, 2018). • Studies will be evaluated using specific data evaluation criteria. • Study results will be extracted and presented in evidence tables by cancer endpoint. 2) Evaluate the weight of the scientific evidence of human health hazard data. • EPA will rely on the weight of the scientific evidence when evaluating and integrating human health hazard data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence. • Assess dose-response information to refine quantitative unit risk for lung cancer and mesothelioma. Review the appropriate human data identified to update, or reaffirm, the 1988 quantitative estimate of the unit risk of asbestos-related lung cancer and mesothelioma by the inhalation route. 3) In evaluating reasonably available data, EPA will determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.
While TSCA section 26(h) establishes "scientific standards" for science-based decisions under section 6 and other provisions, these standards are general and flexible and do not materially change longstanding criteria used by agencies and the scientific community to assess the reliability, relevance and completeness of scientific evidence. The TSCA standards are consistent with the data review methodologies used by IRIS, other EPA programs and expert organizations like NTP and provide no justification for questioning science judgments and study interpretations made in the IRIS process.

Y
Y

304	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy
305	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy
306	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy
307	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure

N/A
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Even without IRIS assessments, the risks of many substances have been thoroughly reviewed and determined by the Agency and other authoritative bodies but these earlier findings will now be subject to revision as EPA reinterprets studies using its TSCA systematic review document. For example, 1-Bromopropane is classified by the National Toxicology Program as "reasonably anticipated" to cause cancer in humans. In 2016 the EPA Draft Risk Assessment recognized the relevance and reliability of this health endpoint when it derived an inhalation unit risk estimate based on lung tumors. So, it is particularly disturbing that the problem formulation for this chemical states that the "the weight-ofevidence analysis for the cancer endpoint is inconclusive" and it will be evaluated using the flawed TSCA systematic review (EPA 2018 Problem Formulation, p. 45). The concern raised by SCHF, NRDC, and others regarding the industry bias of the TSCA systematic review document makes it likely that a reanalysis will result in a false negative – that is, discounting evidence of cancer (see comments on TSCA systematic review by SCHF, NRDC, Docket EPA-HQ-OPPT-2018-0210 incorporated by reference).
In sum, we strongly oppose any reopening of IRIS or other findings that have been finalized and represent authoritative determinations by the Agency. As it proceeds with the risk evaluations, EPA should rely on previous IRIS assessments except where significant new data are available. In this case, the IRIS program should evaluate whether the new data warrants modification of its previous determinations of the weight of the evidence for specific endpoints.
It would be both scientifically indefensible and counterproductive for the Agency to reopen these assessments for yet another round of public input and to redo the extensive analyses they contain simply so industry commenters can have another bite at the apple on findings they dislike. The next step in the rulemakings should be to issue final rules as quickly as possible. These rules, once issued, should close the book on the targeted uses and enable EPA to focus its risk evaluations on uses that have not yet been assessed.
XII. EPA Should Not Presume That Occupational Exposure Standards Are Fully Protective of Workers, Can be Equated with the Absence of Unreasonable Risk and are Representative of Actual Worker Exposure Occupational exposure is significant for nearly all of the 10 chemicals and should be a major focus of EPA's risk evaluations. The problem formulations indicate that when evaluating occupational risks, the Agency will heavily weigh mandatory and voluntary workplace standards and "will consider the influence of the recommended exposure limits on occupational exposures." We agree that existing workplace standards are relevant in determining risks to workers. However, for several reasons, it would be unjustified for EPA to presume that these standards are fully protective of workers or that their existence can be equated with the absence of unreasonable risk.

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308	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Exposure
309	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Exposure
310	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Exposure

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First, TSCA and the Occupational Safety and Health Act (OSH Act) apply differing standards of protection and the level of risk reduction afforded by OSHA limits may well be inadequate to satisfy the more stringent requirements of TSCA. OSHA is only authorized to adopt workplace standards for chemicals presenting "significant risks of harm," a term interpreted by the Supreme Court's Benzene decision as requiring OSHA to demonstrate by substantial evidence that "it is at least more likely than not that longterm exposure to [a chemical] presents a significant risk of material health impairment." By contrast, the term "unreasonable risk" under TSCA does not impose this high threshold for regulation. Further, OSHA may impose only economically and technologically feasible limits on exposure. However, economic and technological considerations have no bearing on EPA's determinations of unreasonable risk, which cannot take into account cost and other non-risk factors under section 6(b)(4)(A).80 Finally, while OSHA is only authorized to place limits on exposure, TSCA provides a broad array of remedies, including bans of production and use, which may provide a level of protection that OSHA lacks authority to impose. Footnote: 80 Based on these considerations, EPA decided against referring to OSHA workplace risks from exposure to trichloroethylene (TCE) under section 9(a) of TSCA, even though OSHA had earlier promulgated a workplace standard for TCE. In deciding to address risks to workers through a section 6(a) rulemaking instead, EPA compared its authority under TSCA to eliminate these risks to that of OSHA, concluding that "there is no other federal law that provides authority to prevent or sufficiently reduce these . . . exposures." It further concluded that risks that EPA found to be "unreasonable" under TSCA might not be deemed "significant" by OSHA. 82 Federal Register 7432, 7454 (January 19, 2017).
Second, a number of the OSHA standards that apply to chemicals subject to the first 10 risk evaluations were developed many years ago and do not reflect current data and scientific understanding of the health effects of the regulated chemicals.81 Thus, the levels of exposure allowed by these standards may be unsafe when evaluated using the best available science. Footnote: 81 OSHA has two types of standards. Under section 6(a) of the OSH Act, OSHA adopted hundreds of PELs in 1971 that were, at that time, considered national consensus standards. They have not been updated since and are based on science from the 1960s or earlier. Since 1971, OSHA has regulated only about 40 chemicals under section 6(b). These more comprehensive standards are based on thorough evaluation of health effects and a determination that risks are significant. OSHA has 6(b) standards regulating only asbestos and MC. It has PELs (adopted under 6(a)) for PERC and TCE but not for the other 10 chemicals. In the case of both asbestos and MC, OSHA's published Federal Register preambles found that even at the revised PEL, employees continued to be exposed to significant risks i.e., risks above 1/1000 – OSHA's definition of significant risk.
Third, OSHA does not cover all workers. It only covers private sector employees of employers. It does not cover employees of federal, state or local governments. These workers might include building maintenance people exposed to asbestos, hospital workers exposed to PERC when laundering linens or other supplies, etc. OSHA also does not cover independent contractors. In the construction sector, many people performing remodeling work, such as stripping paint and otherwise using MC, or removing asbestos insulation are independent. These workers have no OSHA protection. So even if OSHA standards were adequately protective of the workers they covered, there would still be a need for EPA to act under TSCA to make sure all workers had an equivalent level of protection.

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311	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Exposure
312	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure

2.2, 2.3
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Fourth, there is no basis for EPA to assume across-the-board compliance with OSHA standards. As the Agency pointed out in its proposed section 6(a) rule for MC paint removal products, exposures above the OSHA limit have been well documented.82 To determine actual workplace exposures, we encourage EPA to obtain and review all the data gathered by law under OSHA's Access standard, 29 CFR 1910.1020 which "provide[s] employees and their designated representatives a right of access to relevant exposure and medical records; and to provide representatives of the Assistant Secretary a right of access to these records in order to fulfill responsibilities under the Occupational Safety and Health Act."83 (1910.1020(a)). This would provide a basis for comparing actual exposures to OSHA standards and, for specific chemicals, determine whether and to what extent OSHA standards reliably limit exposure. While these data will provide a valuable snapshot of exposures, it should be kept in mind that OSHA exposure monitoring data is not systematic or comprehensive, and therefore may not be representative of workplace chronic or peak exposures that are likely to be missed with snapshot monitoring. Footnotes: 82 Studies referenced by EPA found widespread non-compliance with the OSHA MC workplace standard during paint and coating removal, resulting in MC exposures above the OSHA standard, despite the mandatory nature of the OSHA requirements. 82 FR 7405 (Ref. 70) 83 These data include: • "Environmental (workplace) monitoring or measuring of a toxic substance or harmful physical agent, including personal, area, grab, wipe, or other form of sampling, as well as related collection and analytical methodologies, calculations, and other background data relevant to interpretation of the results obtained" (1910.1020(c)(5)(i)); and, • "Biological monitoring results which directly assess the absorption of a toxic substance or harmful physical agent by body systems (e.g., the level of a chemical in the blood, urine, breath, hair, fingernails, etc.)" (excluding drug and alcohol testing) 1910.1020(c)(5)(ii). For example, the OSHA standard for methylene chloride can be found at 29 CFR 1910.1052, which describes details of mandatory exposure monitoring, employee notification requirements, and long-term retention of the monitoring results. Under OSHA's Access standard, 29 CFR 1910.1020 (D)(7)(ii), employers must retain these records for 30 years.
Finally, as EPA has recognized, some of the industrial hygiene strategies embodied in OSHA standards – such as labels and respirators – are known to be of limited effectiveness in protecting workers and have been required by OSHA to compensate for the lack of effective engineering controls or constraints on its authority, not because they are uniformly protective. For example, in its proposed section 6(a) rules for TCE, MC and NMP, EPA analyzed a universe of 48 studies [84] and concluded that: • [C]onsumers and professionals do not consistently pay attention to labels; consumers and professional users often do not understand label information; consumers and professional users often base a decision to follow label information on previous experience and perceptions of risk; even if consumers and professional users have noticed, read, understood, and believed the information on a hazardous chemical product label, they may not be motivated to follow the label information, instructions, or warnings; and consumers and professional users have varying behavioral responses to warning labels, as shown by mixed results in studies. Footnote: 84 OPPT summarized these studies in a paper entitled: The Effectiveness of Labeling on Hazardous Chemicals and Other Products (March 2016) (Ref. 33 in rulemaking docket).

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313	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure
314	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Exposure
315	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General

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Similarly, EPA cautioned that "there are many documented limitations to successful implementation of respirators," explaining that: "Not all workers can wear respirators. Individuals with impaired lung function, due to asthma, emphysema, or chronic obstructive pulmonary disease for example, may be physically unable to wear a respirator. Determination of adequate fit and annual fit testing is required for a tight fitting full-face piece respirator to provide the required protection. Also, difficulties associated with selection, fit, and use often render them ineffective in actual application, preventing the assurance of consistent and reliable protection, regardless of the assigned capabilities of the respirator. Individuals who cannot get a good face piece fit, including those individuals whose beards or sideburns interfere with the face piece seal, would be unable to wear tight fitting respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue and reduced work efficiency (63 FR 1156, January 8, 1998). According to OSHA, 'improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health. (63 FR 1189-1190)."
Because of these considerations, EPA cannot assume that, simply because they are required by OSHA standards, labeling or respirators will in fact provide adequate worker protection and successfully prevent unsafe exposure. Rather, as it did in its proposed rules for MC, TCE and NMP, EPA should explicitly recognize the limitations of these industrial hygiene controls and determine whether risks to workers are unreasonable given that labeling and respirators are often unprotective and unreliable in the real world.
Conclusion The EPA problem formulations are replete with questionable exclusions and loopholes, failures to require necessary testing, deviations from accepted scientific methods and refusal to accept previous peer reviewed determinations of risk. As a result, the Agency is on a path to produce evaluations that ignore important exposure pathways and at-risk populations, disregard evidence of adverse effects and reach misleading, incomplete and understated conclusions about risk that weaken public health protection. EPA should put the 10 evaluations on hold, rethink how they are being conducted, and reinitiate them in accordance with the law and principles of sound science.

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Systematic Review - Public Comments on the Application of Systematic Review in TSCA Risk Evaluation

FULL LIST OF COMMENTS

#	Submitter	Attachments (#)	Category (RegNex, Editorial, Exposure, Fate, Engineering, Human Health, Eco Health, PESS, Policy, Other, Systematic Review, General)	Document Section #
1	ACC	3	Systematic Review	N/A
2	ACC	3	Systematic Review	N/A
3	ACC	3	Systematic Review	N/A
4	ACC	3	Systematic Review	N/A
5	ACC	3	Systematic Review	N/A

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Comment
ACC appreciates the transparency and progress toward documentation of the TSCA systematic review approach. EPA has developed a strong baseline systematic review approach, emphasizing the importance of allowing for "fit-for-purpose" evaluations tailored to specific substances and an iterative evaluation process. The guidance outlined for data searches, data screening, and data extraction is comprehensive and useful. Notably, the current guidance has a strong focus on study quality, and thoroughly outlines the proposed steps for study quality evaluation for each domain of evidence.
However, there are some critical systematic review concepts and methodologies that remain to be discussed or fully developed in the current approach document, most notably for the process of evidence integration. Following the consideration of initial comments received, and the further development of the approach in the draft risk evaluations for the first 10 chemicals, EPA should re-issue the systematic review framework document with appropriate updates and allow for additional review and stakeholder feedback. In particular, at that time, EPA should put forward the standardized procedures the Agency will use for integrating evidence that ensures consistent use of best available science, weight of the scientific evidence, and, as applicable, an understanding of mode of action (MOA).
The systematic review process should have sufficient flexibility such that it can adapt to the realities of the chemicals being tested and the limitations in experimental methodology and laboratory techniques. For example, the challenges in collecting hazard, fate, and exposure data for chemicals with any one of a number of characteristics which make them “difficult substances” for testing purposes are well known. Results from common adaptations of typical test methods for difficult substances should not be blindly rejected but should be subject to expert judgment to confirm the validity and applicability of such data.
EPA should add discussion emphasizing the importance of incorporating information on MOA data in problem formulation, and consider organizing the problem formulation step around these data, even if the MOA is not entirely clear from the outset. Existing frameworks, such as the World Health Organization (WHO)/International Program on Chemical Safety (IPCS) MOA/Human Relevance (HR) Framework, the Adverse Outcome Pathway (AOP)framework, or other similar approaches may be useful.
Within the problem formulation phase of the evaluation, EPA must clearly describe any decisions regarding its planned use of other EPA office or agency assessments of the chemical under review. Further, OPPT should not automatically adopt existing toxicity criteria in the absence of its own review and consideration of possible alternative values using the proposed systematic review approach.

RAD POC	Docket #	Action Needed

6	ACC	3	Systematic Review	N/A
7	ACC	3	Systematic Review	N/A
8	ACC	3	Systematic Review	N/A
9	ACC	3	Systematic Review	N/A
10	ACC	3	Systematic Review	N/A
11	ACC	3	Systematic Review	N/A
12	ACC	3	Systematic Review	A.1

We support EPA's intention, as specified in the problem formulation documents, to conduct its own independent assessment of existing toxicity values. In many cases, these existing reviews are dated and were published without the benefit of systematic review and consideration of available studies reflecting the best available science that have been more recently developed.
Regarding the data collection phase, the current approach for data searching, screening, and extraction is well developed. EPA provides detailed information on its plans to use specific search strategies and databases, how decisions will be made regarding screening (in both the abstract/title and full text screening phase), and how it will carry out the quality assurance (QA)/quality control (QC) process for all three parts of data collection. Further, EPA includes example search and screening strategies used for the first 10 chemicals, which provide helpful context on the implementation of this phase of the risk evaluation.
EPA's consideration of grey literature, such as technical reports, conference proceedings, and unpublished industry data, is well supported, as there are many sources that may be useful that have not been published in peer-reviewed journals. In order for this approach to be truly fit for purpose, it is critical that EPA capture studies generated for regulatory purposes at the data collection stage. EPA should also consider the possibility of publication bias in the peer-reviewed literature; i.e., the possibility that studies with negative findings may not have been published.
ACC supports EPA's recommendation that the Agency pilot test the search and screening methods, which will be important for iterative evaluations. This will allow for changes to be made if it becomes clear that references have been missed by the use of specific search terms, or if relevant articles are being unintentionally screened out. Further, it is critical that EPA thoroughly describe the reasoning for any changes to risk evaluations resulting from pilot testing or other iterative phases of the assessment. Clarification is also needed as to how EPA will carry out iterative methods in later phases of an evaluation.
Overall, the systematic review approach covers essential aspects of evaluating study quality. It indicates that EPA intends to thoroughly evaluate and fully consider the implications of the quality and relevance of the available evidence before incorporating it into its risk evaluations. There are many positive attributes in the methods EPA describes, such as a training phase for reviewers to ensure consistency across quality evaluations. The specific criteria are informed by several existing, well-regarded evaluation systems that detail critical study quality and reporting criteria systems, such as the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement and the Biomonitoring, Environmental Epidemiology, and Short-lived Chemicals (BEES-C) instrument.
The study quality evaluation process appears to be very time intensive, and it is unclear whether it is possible to complete it in full for every evidence type for each evaluation, given the tight regulatory deadlines under TSCA. It is also unclear whether, as an alternative, EPA may rely on existing quality evaluations, and, if so, how these evaluations will be evaluated to ensure they adequately fulfill the rigorous quality assessment requirements proposed for TSCA evaluations.
Page 33 of the systematic review approach states, " EPA/OPPT plans to use data with an overall quality level of High, Mediu, or Low confidence to quantitatively or qualitatively support the risk evaluations, but does not plan to use data rated as Unacceptable." ACC agrees that unacceptable data should not be used in the risk evaluation.There is some concern that low confidence studies could be used to quantitatively support a risk evaluation. If there is low confidence in the study methods and/or reporting, then it should not be used to quantitatively support the derivation of a point of departure in a hazard assessment. Rather, it should be used qualitatively as a supporting study or in a weight-of-evidence determination for hazard characterization.

13	ACC		3	Systematic Review	Appendix A
14	ACC		3	Systematic Review	Appendix A
15	ACC		3	Systematic Review	Appendix A
16	ACC		3	Systematic Review	N/A

EPA states that it will not automatically assign lower confidence to studies not adhering to Good Laboratory Practice (GLP) or Organisation for Economic Co-operation and Development (OECD) guidelines, but rather, it will consider, "any and all available, relevant data and information that conform to the TSCA science standards" as acceptable. What this might mean for academic studies, which are usually not conducted according to GLP requirements and may use non-standard methods, is unclear. EPA should ensure that the study quality evaluations retain consideration of the robust and highly documented process required by GLP guidelines, even if they are not GLP studies. As noted by Borgert et al., 2016, "...regulatory agencies have placed a high value on study reports that include sufficient detail to allow reanalysis of data to independently confirm results and support additional analysis using alternative methods of data evaluation." Borgert and co-authors also emphasize that GLP-compliance is much more than record keeping and reporting.
Overall, the scoring examples shown are clearly and transparently laid out in a series of tables. The weighting scheme, metrics, and overall scoring are relatively straightforward.ACC appreciates EPA's intention to be highly transparent and consistent in its evaluations through the use of a quantitative study scoring system. However, the scoring system described in the current approach is complicated by many possible options that may or may not be used, such as weighting factors. This may result in very specific scores with a relatively narrow range, which may make interpreting studies of similar but not identical quality difficult (e.g., a score of 1 versus 1.7). Further, some of the weighting factors chosen involve substantial scientific judgment, and EPA should consider that some metrics may be more important to overall quality for specific studies, relative to others, indicating that a generic "one-size-fits-all" weighting factor could become problematic. For example, in the criteria for occupational exposure and release data evaluation, it is unclear why the metric of methodology in the reliability domain is given a weighting factor of 1, when other critical factors, such as reliability, are weighted at 2. Incorrect or inappropriate methodology could be just as critical of a flaw, if not more so, than some of the other metrics.
In addition, while the use of a 1-4 scale for judging whether a study is evaluated to have high confidence, medium confidence, low confidence, or be unacceptable for use is clearly laid out and justified, it is anticipated that there could be some confusion with the already much-used Klimisch system of study evaluation.18 The Klimisch system is somewhat similar in that studies assigned a 1 or a 2 are considered reliable without restrictions, or reliable with restrictions, respectively. However, the Klimisch system differs from the one EPA is proposing by attributing a score of 3 to studies that are not reliable, and a score of 4 designating a score is not assignable due to insufficient information. In other words, the scale used on EPA's approach is the opposite of the Klimisch system for scores of 3 and 4. Furthermore, Klimisch scoring does not use weights or calculate mathematical averages, but rather assigns qualitative overall integer values of 1, 2, 3, and 4. Since the Klimisch scoring is already broadly used in regulatory activities across the globe, EPA should consider harmonization for evaluating studies in order to avoid confusion and harmonize with other geographies.
The availability of data and other information required to verify and reproduce critical studies in the risk evaluation is also important. Any data that are used to derive toxicity criteria should be made publicly available to the greatest degree possible, while still protecting confidential business information (CBI) and other sensitive personal information, consistent with EPA's recently proposed rule on Strengthening Transparency in Regulatory Science. This will facilitate transparency and allow others to consider and independently evaluate the quality, reliability, and interpretation of these data. For example, a frequent concern with published academic studies is that the data presented in either tabular or figurative form have already experienced some form of statistical transformation. In many cases, even an expert-level statistician cannot recreate the original data from these data.

17	ACC	3	Systematic Review	N/A
18	ACC	3	Systematic Review	3.4
19	ACC	3	Systematic Review	3.4
20	ACC	3	Systematic Review	3.4
21	ACC	3	Systematic Review	3.4
22	ACC	3	Systematic Review	3.4

Academic laboratories sometimes conduct their statistical analysis using laboratory personnel who are not professional statisticians. The technical issue with non-professional analysis is rarely whether the test was conducted correctly, but rather whether the most appropriate statistical test was selected. In a seminal study conducted by Begley and Ellis (2012), the study authors were unable to replicate the results from statistical analyses of 47 of 53 landmark pre-clinical cancer research papers. This led to a flurry of other studies in different fields that have also reported similar findings. Thus, it is crucially important that data upon which regulatory actions are based be available for independent statistical analysis.
In the current systematic review approach document, the strategy for evidence integration lacks detail and specificity. Only general, high-level principles are described, and no specific weight-of-evidence methodology is presented as a baseline for TSCA assessments. EPA recognizes that the evidence integration phase of assessments is underdeveloped and indicates that it anticipates defining and demonstrating the process of integration in the forthcoming first 10 chemical draft risk evaluations. We expect that as EPA gains more experience with evidence integration, and can describe the standardized procedures the Agency will use for integrating evidence that ensures consistent use of best available science, weight of the scientific evidence, and, as applicable, understanding of MOA, the Agency will revise this guidance document. Such a revision should include additional review and public comment.
First, EPA should use a transparent process to integrate evidence that is standardized in such a way to allow for greater efficiency. EPA should consider development of a structured narrative that fully describes how the different pieces of available evidence support a given conclusion/argument or an alternative. In this way, EPA can clearly demonstrate how specific studies or data sources contributed to the final conclusion. This will ensure that the process by which EPA reaches conclusions about exposure, hazard, and/or risk will be well developed and transparent.
Second, as a part of the evidence integration narrative, EPA should clearly describe how the study quality evaluations will be used to weigh the evidence and reach conclusions for the different phases of the risk evaluation, including exposure assessments, hazard assessments, and any quantitative estimates of risk. For example, the current approach does not indicate whether a high-confidence study will always be given more weight than a medium-confidence study in formulating conclusions, or how other factors, such as study relevance, will be weighed with quality considerations. EPA should consider building from the published approaches for quantitative weight-of-evidence analysis, such as Bridges et al., 2017; Becker et al., 2017; and Dekant et al., 2017.
Third, EPA should detail how it will conduct uncertainty analyses and communicate these uncertainties consistently and transparently in each risk evaluation.
While MOA/AOP evidence and mechanistic data are mentioned in several places in the systematic review approach, EPA should consider expanding its discussion of this important evidence, particularly in the evidence integration phase of evaluation. MOA/AOP evidence and mechanistic data should be weighed concurrently with observational and toxicology evidence and considered a critical organizing principle for the weight-of-evidence evaluation.

23	ACC	3	Systematic Review	3.4
24	ACC	3	Systematic Review	3.4
25	ACC	3	Systematic Review	3.4
26	ACC	3	systematic Review	3.4
27	ACC	3	Systematic Review	3.4

The AOP framework can be employed specifically as an organizing principle that explains MOA and the connections to adverse outcomes. The AOP framework is a tool to systematically organize available data and knowledge that describes scientifically plausible and causal relationships across multiple levels of biological organization between a molecular initiating event (MIE) and subsequent key events (KEs), culminating in an adverse outcome (AO) potentially relevant to risk assessment. EPA researchers have been instrumental in developing AOPs and tools to facilitate the further development, review, and use of AOPs in scientific and regulatory endeavors. Tools such as the AOP wiki can be mined for additional data and organizational principles as well as domains of applicability for various identified MOAs associated with chemicals. Thus, whether evidence generally aligns or does not align with any proposed or known MOAs and/or AOPs should be a necessary consideration in integrating evidence to reach conclusions.
Since the scientific justification for assessing human relevance and selecting dose-response extrapolation methods for quantifying potential cancer risks at environmentally relevant levels of exposure is highly dependent upon the determination of the likely operative MOA, the Agency should implement a systematic and explicit approach for evaluating a chemical dataset, using hypothesized MOAs and the evolved Bradford Hill causal considerations, to integrate evidence and derive weight of the evidence confidence scores for potentially relevant MOAs. This approach enables a side-by-side comparison of numerical weight of the evidence confidence scores for different hypothesized MOAs, including the default linear no threshold model. This enhances transparency and improves communication among risk managers and the public. This best available science approach provides a transparent, scientifically sound justification for using the most likely operative MOA as the basis for selecting the most appropriate extrapolation method to then calculate potential risks to humans for environmentally relevant exposures.
In addition, EPA should describe how it will consider issues of the adversity of identified health effects when considering the weight of the evidence. For example, there may be animal studies that demonstrate statistically significant effects that are reversible, and/or epidemiology studies may show changes in blood biomarkers but are not predictive of clinical disease. Results of this nature (those for which the adversity or clinical relevance is either questionable or unclear) should be interpreted with caution when making causal conclusions regarding hazard, and when selecting endpoints for consideration as critical effects.
Finally, EPA should add a discussion of how it will consider questions of relevance in the data evidence integration and summary phases of the risk evaluation. EPA indicates that it will use a tiered approach to check for relevance at various points in each risk evaluation, including during data screening and selection. However, it is not entirely clear how data will be weighed according to relevance when integrating evidence to support conclusions when presumably, at this point in the evaluation, all evidence discussed was previously deemed relevant to the risk evaluation for some purpose.
EPA should consider reviewing and adapting portions of other established systematic review and weight-of-evidence frameworks. For example, one recent and generally well-developed framework is the European Food Safety Authority (EFSA) Guidance on the use of the weight-of-evidence approach in scientific assessments.30 Critical concepts in weight-of-evidence are well described, including the consideration of relevance, reliability, and consistency within and across lines of evidence. Various options for causal frameworks are presented, and EFSA emphasizes that, in many cases, a single method often cannot cover all steps. Differing methods, or a combination of methods, may be needed for a given assessment. These fit-for-purpose decisions can be documented in the problem formulation phase of assessment and thus will be vetted via peer review and public comment.

28	ACC	3	Systematic Review	3.4
29	APHA	1	Systematic Review	N/A
30	APHA	1	Systematic Review	N/A
31	APHA	1	Systematic Review	N/A
32	APHA	1	Systematic Review	N/A

Transparency in the decision-making process is vital for producing scientifically defensible and understandable assessments. Clear, thorough discussions of all decisions will increase confidence and aid in the general acceptance of the findings and conclusions of TSCA risk evaluations. The transparency of overall conclusions on chemical hazard, exposure, and risk may also be enhanced by the use of tabular and/or graphical summaries of the weight-of-evidence conclusions. Further, it is important that in all phases of the assessment, but particularly in the evidence integration and summary sections of the assessment, EPA clearly describes all areas in which expert judgment was utilized.
In addition, the Systematic Review Guidance describes how the agency intends to identify, evaluate, and integrate scientific information for TSCA risk evaluations. The guidance will be pivotal to the conduct and ultimately the scientific credibility of these evaluations. Yet the guidance is inconsistent with the best available science and has not been peer reviewed by independent experts. The current draft diverges from established techniques in use in the scientific community. I urge the agency to comply with its own Peer Review Handbook, to arrange for peer review of the guidance by the National Academy of Science, and to revise the guidance based on the results of this peer review prior to relying upon it to conduct systematic reviews for TSCA risk evaluations.
EPA's Systematic Review Guidance describes how EPA intends to identify, evaluate and integrate scientific information used in TSCA risk evaluations. The guidance will shape, for example, whether and to what extent the agency considers a study finding that exposure to a chemical was associated with a particular adverse health effect. TSCA requires EPA to "use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science" and to "consider as applicable...the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models." § 26(h) (emphasis added). Yet the guidance is not consistent with the best available science nor has it been peer reviewed by independent experts. EPA's reliance on this version of the guidance would violate TSCA.
The guidance is not consistent with best practices for systematic review. The guidance includes hundreds of pages of data quality criteria that EPA will use to assign numeric scores to individual studies. The agency says it may disregard a study based on the numeric score assigned to it. This is an outdated approach. NAS discourages the use of numeric scoring in systematic review, noting that "[i]n recent years, systematic review teams have moved away from scoring systems to assess the quality of individual studies," in part because scoring systems have not been validated and different systems can produce radically different results. Notably, systematic reviews conducted by EPA's Integrated Risk Information System do not utilize numeric scoring, and neither should systematic reviews conducted under TSCA.
Surprisingly, EPA has not subjected the guidance to peer review. This is a major omission. In addition to ignoring TSCA's requirement to consider the extent of peer review of the scientific information and technical procedures used by the agency, relying on the guidance when it has not been peer reviewed would harm the scientific credibility of the TSCA program. As EPA's own Peer Review Handbook states, "Peer review enhances the credibility and acceptance of the decision based on the work product," which in this case is the decision to regulate or not regulate a chemical under TSCA based on a risk evaluation and determination. EPA should seek peer review of the guidance by NAS, which has published several reports on the conduct of systematic review for chemical exposure and its application by federal agencies.

33	API	1	Systematic Review	N/A
34	API	1	Systematic Review	N/A
35	API	1	Systematic Review	N/A
36	API	1	Systematic Review	N/A
37	API	1	Systematic Review	p.35
38	API	1	Systematic Review	N/A

API supports EPA's efforts to develop a Policy for Systematic Review in TSCA Risk Evaluations that is consistent and that increases transparency and reduces regulatory uncertainty for stakeholders. API recognizes several positive aspects of OPPT's Systematic Review Policy. The Policy is guided by problem formulation and is based on the best available science and a weight-of-the-evidence (WOE). An emphasis is placed on evidence quality to ensure a quality review. There is a proposed pilot test of criteria for title and abstract screening and tagging. Emphasis is also placed on human health and ecological toxicity testing data meeting minimum reporting criteria (which are necessary for evaluating study quality) and alternative approaches are included. API recognizes that systematic review should, in theory, increase transparency and reduce regulatory uncertainty for stakeholders. API has considered this draft Policy in the context of other established metrics for study quality and approaches to systematic review and has also identified aspects of this draft Policy that would benefit from further clarification.
1. EPA/OPPT's quantitative data evaluation method appears to differ from other established methods and also from the qualitative, yet structured approaches used by EPA/IRIS and others. It is unclear how feasible it will be in practice and the impact on risk assessments.
EPA/OPPT's quantitative data evaluation method appears different from other established methods such as the Klimisch scoring system, OECD guidance for (Q)SAR models3, the Criteria for Reporting and Evaluating Ecotoxicity Data (CRED), etc. The quantitative data evaluation method (individual metrics and domains) for different kinds of data results in apparent inconsistencies, examples of which are provided in point 2) below. The draft Policy is also unclear on how the study scores will be used in the evidence integration and WOE evaluation. For example, it is unclear if a quality weight risk measure will be calculated or if results will be stratified by score. Clarifying information on how quality scores will be used in this draft Policy or in future science policy documents would be helpful in this regard.
API notes that the use of a quantitative approach by EPA/OPPT is inconsistent with a trend toward using more qualitative, structured approaches used by EPA/IRIS and as described in the ROBINS-I tool for assessing bias and in the Cochrane GRADE Handbook. The structure of these more qualitative approaches allows greater latitude for expert judgement without necessarily sacrificing transparency and reproducibility.
EPA/OPPT states as an Important Caveat that "The weighting approach for some of the strategies may need to be adjusted as EPA/OPPT tests the evaluation method with different types of studies." (Page 35). Based on this statement, it does not appear that EPA/OPPT has tested this quantitative data evaluation method on historical data to determine how feasible it is in practice and how it may impact risk assessments conducted under TSCA. Thus, the efficacy and practicality of this approach seem largely unknown, although there are some foreseeable challenges. One foreseeable challenge is how studies that score the same and yet support different very conclusions will be resolved. Another foreseeable challenge is reproducibility in study scoring, both within EPA and externally if stakeholders undertake their own scoring exercises based on EPA criteria. Reproducibility becomes particularly important if differences in study scoring could substantively impact critical aspects of a risk assessment (e.g., endpoints, exposure levels, etc.). These and other foreseeable and unforeseeable challenges could require that the approach be dramatically adjusted such that the final working version is very substantially different from the current draft. To the extent that study scoring impacts risk assessments, there may be inconsistencies in risk assessments as the draft Policy evolves.
2. EPA/OPPT's quantitative data evaluation methods appear inconsistent

39	API	1	Systematic Review	p.32
40	API	1	Systematic Review	p. 76
41	API	1	Systematic Review	N/A

EPA/OPPT's quantitative data evaluation methods appear inconsistent. The draft Policy states: "The TSCA evaluation strategies in some cases refer to study guidelines along with professional judgement as a helpful guidance in determining the adequacy or appropriateness of certain study designs or analytical methods. This should not be construed to imply that non-guideline studies have lower confidence than guideline or Good Laboratory Practice (GLP) studies. EPA/OPPT will consider any and all available, relevant data and information that conform to the TSCA science standards when developing the risk evaluations irrespective of whether they were conducted in accordance with standardized methods (e.g., OECD test guidelines or GLP standards)." (Page 32).
This implies that studies will not be excluded simply because they are not guideline and/or GLP and that non-guideline/non-GLP studies can rate quite highly if they meet certain criteria. The draft Policy is inconsistent in the degree to which adherence to, or consistency with, standard methods or test guidelines impacts the metrics for particular kinds of data/information. For some kinds of data/information, adherence or similarity to standard methods is required to achieve a high rating (and example of this is monitoring data[7]). For others (e.g., animal and in vitro toxicity data), test guidelines are either not mentioned and appear to be instead substituted with metrics that contain elements similar to those contained in guideline studies (animal toxicity data)[8] or consistency with guideline studies is used as an indicator of quality (in vitro toxicity data)[9]. When test guidelines are available for both animal and in vitro toxicity studies, it seems inconsistent that adherence to or consistency with a guideline would impact study metrics for in vitro studies but not animal studies. **<u>Footnotes:</u>** [7]Table D-11, Evaluating Criteria for Monitoring Data states that "Sampling or analytical methodology is an approved OSHA or NIOSH method or is well described and found to be equivalent to approved OSHA or NIOSH methods" in order to achieve the highest Confidence Level (Score=1) under Domain 1. Reliability (Page 76). [8]Test guidelines are not mentioned in the Table G-14 Data Quality Criteria for Animal Toxicity Studies, even though numerous test guidelines for animal toxicity studies are available. Instead, study elements commonly addressed in test guidelines and GLP studies appear to have been included as data quality criteria, although this inclusion may not be comprehensive. [9]Table G-16, Data Quality Criteria for In Vitro Toxicity Studies, consistency with current standards and guidelines can impact Confidence Level scores in several areas (e.g. Metrics 7,11,15, and 23).
3. It is unclear if EPA will still require studies that are guideline/GLP under TSCA.

42	API	1	Systematic Review	N/A
43	API	1	Systematic Review	N/A
44	API	1	Systematic Review	N/A
45	API	1	Systematic review	N/A

As already mentioned in 2) above, it seems clear that EPA will consider studies that conform to TSCA science standards regardless of if they are guideline/GLP. Some elements of guideline studies appear to be captured in study metrics. However, API was unable to identify any study metrics that captured elements of GLP studies, such as provisions for EPA to access/audit raw data or quality assurance requirements that includes recordkeeping, instrument calibration, and study conduct by persons with appropriate education, training, and experience. Although non-GLP studies may very well have some or all of these benefits, providing these is voluntary, whereas for GLP studies doing so is required. GLP studies done according to established test guidelines add significantly to the cost of research but have historically been considered high quality data for regulatory use and have been required by EPA. The statement above indicates that this may no longer be the case and that regulatory acceptability and use of studies by EPA will now be determined more by compliance with the TSCA evaluation strategies described in this draft Policy than by adherence to test guidelines and GLP. Clarification regarding whether or not this is the case may assist stakeholders in decisions regarding future study design.
4. EPA/OPPT's quantitative data evaluation method may be problematic for complex substances such as UVCB Substances.
The test substance identity and characterization criteria (as currently written) may pose challenges for UVCB Substances and result in a review that scores a UVCB with low confidence based on the current descriptions provided in the evaluation criteria tables. For example, some of the criteria described place modeled data as "low" quality when "Data are estimated (modeled) for the subject chemical substance" and measurement is required for a high data quality rating. However, no provisions are made in the criteria for the use of models that are well accepted. Additionally, in Table C-10, the draft Policy specifies a High Score for metric 1: Test substance identity when "The test substance was identified definitively" (including identification by CASRN) "and the specific form characterized, where applicable". A footnote or short explanation that addresses UVCBs is suggested in order to prevent reviewer confusion regarding the phrase" and the specific form characterized, where applicable" because UVCBs would ikely be exempt as there is no sepcific form to characterize.
5. EPA/OPPT's quantitative data evaluation method may be problematic for the "Up-and-down" procedure and other '3R' (reduction, refinement, replacement) methods.

46	API	1	Systematic review	N/A
47	EDF	1	Systematic Review	N/A
48	EDF	1	Systematic Review	N/A

In Table G-13, Serious Flaws that Would Make Animal Studies unacceptable , for the Domain/Metric of Test organisms/Number of animals per group, the draft Policy states that the following would be a Description of Serious Flaw(s) in Data Source: " ... the number of animals per study group was insufficient to characterize toxicological effects (e.g., 1-2 animals in each group). As currently written it seems possible that studies that use the '3R' methods that reduce animal use could be regarded as having a serious flaw under this draft policy. Many of these '3R' methods are supported by analyses that compared the results of the '3R' method to those of the classical test that uses more animals and have been determined perform similarly. This is the case for the "Up-and-Down" proceure for acute oral toxicity tests (Bruce 1987, Yam et al. 1991, Lipnick et al. 1995). A situation in which few animals per dose group and overall are used (in what could technically be regarded as an underpowered study), yet which is bolstered by additional analysis and evidence of similar performance is arguably different for a situation in which a study is underpowered without any additional supporting analyses to indicate that the results would still be reliable. API notes that EPA currently accepts the "Up-and-Down" procedure for acute oral toxicity tests even though only one animal per dose group may potentially be used, and that "It replaces the traditional aacute oral toxicity test formerly used to characterize industrial chamicals, pesticides, and their mixtures." API could find no language in the draft Policy that exempts guideline studies from this metric that use reduced numbers of animals per dose group in a manner that is in accordance with pre-existing EPA science policy. Such languange would serve to provide clarity to both EPA staff and stakeholders on this issue, as well as to further the use of new approach methodologies (NAMs) as described in the 22 June 2018 "Starategic Plan to Promote the Develoipment and Implementation of Alternative Test Methods Within the TSCA Program" (EPA-740-R1-8004).
In May 2018, EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) released its Application of Systematic Review in TSCA Risk Evaluations (hereafter "TSCA systematic review document"). This document provides details regarding the Office of Pollution Prevention and Toxics's (OPPT) development of a proposed "systematic review" approach, and the application of this approach to chemical risk evaluations under the Toxic Substances Control Act (TSCA). EPA states that it will apply this approach to the first ten chemicals undergoing risk evaluation under TSCA. OPPT indicates that it has developed a systematic review approach in order to meet the TSCA requirement that "EPA use data and/or information (hereinafter referred to as data/information) in a manner consistent with the best available science and that EPA base decisions on the weight of the scientific evidence." (p. 14) In the final rule Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, the agency defines weight of the scientific evidence as "a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance." In addition to being required by the agency's risk evaluation rule, applying a systematic review framework to chemical risk evaluation is consistent with the recommendations of the National Academy of Sciences (NAS) and leading chemical assessment initiatives across government and academia.
However, the process that OPPT has outlined in this document omits key aspects of what is entailed in a systematic review – even by the agency's own definition. Among other aspects of systematic review that are missing, the TSCA systematic review document does not describe a general approach to protocol development or data integration. To be consistent with the systematic review, EPA should have developed a protocol for each chemical undergoing risk evaluation. EPA has not developed protocols for any of the first 10 chemicals undergoing risk evaluation.

49	EDF	1	Systematic Review	N/A
50	EDF	1	Systematic Review	N/A
51	EDF	1	Systematic Review	N/A
52	EDF	1	Systematic Review	N/A
53	EDF	1	Systematic Review	Pp.75-76, 79-80, 86-87

Additionally, the one aspect of systematic review OPPT has addressed – evaluation of individual study quality – deviates in several significant ways from established best practices in systematic review. EPA has not provided any empirical evidence or other justification for why these deviations are reasonable, necessary, or scientifically sound. Indeed, EPA has provided no indication that it has even attempted to test its approach on a robust set of actual studies to determine what effect its approach to individual study evaluation will have on study inclusion, evidence integration, and the risk evaluation process more generally.
In sum, the TSCA systematic review document deviates significantly from best practices in systematic review—practices that are empirically based and have been scientifically reviewed, vetted, and instituted by other agencies and authoritative scientific bodies. EPA should substantially revise its TSCA systematic review document and subject it to peer review by qualified external experts in the field.
EPA's proposed approach will lead to violations of EPA's science obligations under TSCA § 26(h), (i), and (k). These directives require that EPA must consider all reasonably available information, and that EPA then must make decisions reflecting the "best available science" and "weight of the scientific evidence" based on the body of evidence as a whole. EPA's proposed approach erroneously tries to apply these directives at the level of individual studies, and the result is that EPA may exclude reasonably available information on the grounds that an individual piece of evidence is somehow imperfect, even when it contributes to the "best available science" or adds to the "weight of the scientific evidence" when available information is considered as a whole.
These statutory commands in TSCA repeatedly emphasize that EPA must make decisions based on the information that is "available," and the courts have recognized that such a duty requires action on the basis of available information even if that information is imperfect. EPA cannot craft its systematic review process to incrementally exclude available information study-by-study, with the possibility of prohibiting use of the best available science simply because one or more of the underlying studies is imperfect in some manner. While certain systematic review approaches in exceptional cases may exclude from further consideration some studies because they entail a substantial risk of bias or have severe methodological shortcomings, EPA's proposed scoring approach appears to allow or require EPA to frequently exclude studies based solely on reporting flaws or other flaws that do not rise to the level of these exceptions.
As described more below, EPA's approach will also exclude certain reasonably available information on the basis that it does not meet EPA's preset expectations. For example, for monitoring data, environmental release data, completed exposure or risk assessments, and reports containing other exposure or release data, EPA plans to rate as "unacceptable" any data derived from occupational or non-occupational scenarios that do not precisely correspond to an occupational scenario EPA has identified within the scope of a given risk evaluation. Pp.75-76, 79-80, 86-87. The far more appropriate response to discovering reasonably available information revealing scenarios outside the scope of the risk evaluation would be for EPA to consider whether it needs to expand the scope of the risk evaluation and potentially the protocol (where any such changes would be clearly documented); nothing in TSCA authorizes or requires EPA to simply ignore that reasonably available information on the basis that it does not meet EPA's preset expectations.

54	EDF	1	Systematic Review	N/A
55	EDF	1	Systematic Review	N/A
56	EDF	1	Systematic Review	N/A

EPA’s TSCA systematic review document is not representative of a true systematic review method as required by EPA’s own risk evaluation rule, which requires inclusion of a “pre-established protocol” that addresses, among other things, how EPA will “integrate evidence”. Born out of the clinical sciences, systematic review employs structured approaches to evidence identification, evaluation, and synthesis in a manner that promotes scientific rigor, consistency, transparency, objectivity, and reduction of bias. Indeed, systematic review transformed the field of medicine—serving today as the method for evaluating the effectiveness of interventions and diagnostic tools. Prominent systematic review methods and tools in medicine, particularly Cochrane and GRADE, have been shaped and refined over several decades based on empirical evidence and experience in application. Appropriately, leading systematic review approaches that have emerged in environmental health, including the UCSF Navigation Guide and the National Toxicology Program’s literature-based reviews, have modeled themselves from these methods.
Bizarrely, EPA correctly cites authoritative sources on systematic review and at points describes processes that generally align with best practices, but then deviates substantially from those established best practices in detailing its specific plans for systematic review. Further, EPA provides no explanation or justification for its deviations.
OPPT’s approach to systematic review lacks a generally linear progression, inconsistent with the conduct of true systematic review. In section three, Integration of Systematic Review Principles Into TSCA Risk Evaluation, EPA includes key excerpts from the preamble to the final rule Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act: "As defined by the Institute of Medicine, systematic review “is a scientific investigation that focuses on a specific question and uses explicit, pre-specified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies” (National Academy of Sciences, 2017). The goal of systematic review methods is to ensure that the review is complete, unbiased, reproducible, and transparent (Bilotta et al., 2014).****Key elements of systematic review include: a clearly stated set of objectives (defining the question); developing a protocol that describes the specific criteria and approaches that will be used throughout the process; applying the search strategy in a literature search; selecting the relevant papers using predefined criteria; assessing the quality of the studies using predefined criteria; analyzing and synthesizing the data using the predefined methodology; [and] interpreting the results and presenting a summary of findings. (p. 13-14)."

57	EDF		1	Systematic Review	p. 13-14
58	EDF		1	Systematic Review	N/A

These excerpts (in comment 56) by and large reflect core tenets and approaches of a systematic review framework. However, the TSCA systematic review document makes evident that EPA has no interest in authentically applying systematic review. Indeed, it would be wrong to call what EPA has developed a systematic review framework, method, or tool. This becomes very evident in Figure 3-1 of the document, TSCA Systematic Review Process, copied below. The graphic portion of the figure illustrates a generally linear process in alignment with a true systematic review framework. However, an examination of the footnotes makes evident that the figure is a mirage: -Footnote b: Data extraction may occur before or after data evaluation. -Footnote c: Evaluation may occur during the scoping/problem formulation phase and/or during the analysis phase of the risk evaluation. -Footnote d: Data relevancy issues are considered during the Data Screening, Data Evaluation and Data Integration phases. -Footnote e: ***Most of the independent verification of the study results (i.e., study replicability) will be assessed during the Data Integration Step. The effect of the footnotes is to undermine the basic premise and purpose of systematic review—to provide consistency, objectivity, transparency, and reduction of bias in the identification, evaluation, and integration of evidence, as foundationally supported by the development of a pre-defined protocol that articulates how these elements are to work. While it is difficult to parse out the specific meaning of EPA's footnotes, it is evident that the agency intends to jumble the process to such an extent that it is no longer a systematic review.
Also deeply concerning is EPA's use of "replicability" as a standard for independent verification. This is wholly inappropriate as it suggests that a study must be repeated in order to be considered valid or of high quality. A study's validity or quality is not dependent on whether the study and its findings have been repeated as discussed extensively in EDF's comments on EPA's proposal, Strengthening Transparency in Regulatory Science.20 EPA must strike this language in Figure 3-1 and anywhere else it may appear.

59	EDF		1	Systematic Review	p. 19
60	EDF		1	Systematic Review	p.19
61	EDF		1	Systematic Review	p.19

OPPT has failed to develop individual protocols for the first 10 chemicals undergoing risk evaluation. In the TSCA systematic review document, EPA states: "Protocol development is intended to pre-specify the criteria, approaches and/or methods for data collection, data evaluation and data integration. It is important to plan the systematic review approaches and methods in advance to reduce the risk of introducing bias into the risk evaluation process (p. 19, emphases added)". EPA has appropriately emphasized the importance of protocol development in systematic review –including its development at the outset. Authoritative sources on systematic review including Cochrane, National Academy of Sciences, the National Toxicology Program's Office of Health Assessment and Translation (OHAT), and the Navigation Guide all stress the import of upfront protocol development (excertps from each document were included). Despite EPA's acknowledgement of the importance of upfront protocol development, EPA has failed to develop such protocols for the first 10 chemicals and it is not evident whether EPA plans to do so for future chemical risk evaluations. EPA states: "The first ten chemical substances were not subject to prioritization, the process through which EPA expects to collect and screen much of the relevant information about chemical substances that will be subject to the risk evaluation process. EPA has limited ability to develop a protocol document detailing the systematic review approaches and/or methods prior to the initiation of the risk evaluation process for the first ten chemical substances. For these reasons, the protocol development is staged in phases while conducting the assessment work. (p. 19)" EPA must develop upfront protocols for each chemical undergoing risk evaluation. The National Academy of Sciences in its recent review of the EPA Integrated Risk Information System (IRIS) program, Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation, explained, "***[the] IRIS program is encouraged to complete the public-comment process and finalize the protocol before initiating the systematic review. Doing so will improve transparency in the IRIS process."
Insufficient time is not an acceptable justification for EPA's failure to develop protocols for the first chemicals undergoing risk evaluation. Upfront protocol development is a fundamental feature of systematic review, which EPA by regulation has explicitly included in its definition of the weight of the scientific evidence. Further, the challenges posed by the time constraints were magnified by EPA's illogical decision not to adopt state-of-the-art approaches to systematic review for chemical assessment that have been peer-reviewed, including by the National Academies, and applied and published (i.e., Navigation Guide, OHAT, and IRIS frameworks). Instead, OPPT has inexplicably chosen to develop de novo its own approach to systematic review, the result of which far from resembles a legitimate systematic review.
EPA must develop comprehensive protocols, make them publicly available, and subject them to public comment – prior to initiating subsequent steps of the risk evaluation process. For efficiency, we recommend that EPA simultaneously publish the protocols and chemical scoping documents. This would not be unlike the approach currently taken by the EPA IRIS program, which publishes its assessment plans (scoping and problem formulation) and protocols for public comment in advance of conducting toxicological reviews.

62	EDF	1	Systematic Review	p. 27
63	EDF	1	Systematic Review	p.27
64	EDF	1	Systematic Review	p. 14

OPPT has failed to describe its approach to evidence integration for the first 10 chemicals undergoing risk evaluation. EPA includes an evidence integration element in its systematic review approach (see Figure 3-1), but has failed to provide any substantive details on how it will execute this phase of the review, leaving a significant aspect of the risk evaluation processes a total black box. In the problem formulations for the first ten chemicals, EPA refers to the TSCA systematic review document for more details on how data integration will occur. But OPPT indicates in the TSCA systematic review document:"Data integration activities for the first ten TSCA risk evaluation [sic] are anticipated to occur after the TSCA Problem Formulation documents are released (Figure 1-1). EPA/OPPT will provide further details about the data integration strategy along with the publication of the draft TSCA risk evaluations. (p. 27, emphasis added)"
Beyond the fact that the public review process for the problem formulations did not have the benefit of knowing how EPA would conduct data integration, EPA's plan to describe and implement its approach to evidence integration simultaneously with the publication of the draft risk evaluations is problematic. Specifically, there is a high risk that EPA will inconsistently implement evidence integration across the first 10 chemicals undergoing risk evaluation as different groups of EPA staff concurrently conduct such evaluations absent a general reference methodology; as well as, significant risk for bias to be introduced in the implementation of evidence integration. It is antithetical to systematic review to concurrently develop and execute an entire step of the review process. More broadly, the absence of any description of how evidence integration will occur reflects EPA's general failure to develop, publish, and seek comment on upfront protocols for the chemicals undergoing risk evaluation. At the very least, EPA should immediately describe its general approach to evidence integration, referring to established systematic review approaches, including the OHAT, Navigation Guide, and IRIS methods. EPA should include this general approach in a revised TSCA systematic review document; and going forward, EPA should detail its specific approach to evidence integration in protocols developed for each chemical undergoing risk evaluation.
OPPT's approach to, and implementation of, systematic review should not provide for excessive iteration. In OPPT systematic review doucment, EPA states: "Although not shown in Figure 3-1, iteration is a natural component of systematic review and risk evaluation processes. There could be different reasons triggering iteration such as the failure of retrieving relevant data and information after the initial search and screening activities, which would require repeating the data collection stage of the systematic review process, or refinements to the initial search, screening and extraction strategies. (p. 14)" While adjustments during the conduct of a systematic review are acceptable, these adjustments should not be a frequent occurrence. The intent of systematic review is to create a structured, transparent, objective, and consistent approach to identifying, evaluating, and integrating evidence in a manner that reduces bias. Excessive iteration undermines this core purpose and provides a pathway for bias. Cochrane notes: "While the intention should be that a review will adhere to the published protocol, changes in a review protocol are sometimes necessary. *** While every effort should be made to adhere to a predetermined protocol, this is not always possible or appropriate. It is important, however, that changes in the protocol should not be made on the basis of how they affect the outcome of the research study. Post hoc decisions made when the impact on the results of the research is known, such as excluding selected studies from a systematic review, are highly susceptible to bias and should be avoided."

65	EDF		1	Systematic Review	p. 14
66	EDF		1	Systematic Review	P. 30
67	EDF		1	Systematic Review	P. 30
68	EDF		1	Systematic Review	p.33

This also exemplifies the problems that arise from EPA's failure to develop upfront protocols. Public comment on the upfront protocols would allow EPA to leverage the larger community in developing a rigorous protocol. A more rigorous protocol upfront would likely reduce the need for iteration. Additionally, in the absence of a protocol, it is impossible for the public to determine when and why EPA has modified its systematic review of a chemical. Documentation of changes to protocols is essential and EPA should provide public access to any changes in the protocol. Cochrane notes: "Changes in the protocol should be documented and reported in the 'Differences between protocol and review' section of the completed review, and sensitivity analyses (see Chapter 9, Section 9.7) exploring the impact of deviations from the protocol should be undertaken when possible." Cochrane systematic reviews are uploaded to PROSPERO, "an international prospective register of systematic reviews in health and social care" that creates a permanent record of protocols and allows changes to be tracked. As of 2013, all Cochrane protocols are automatically registered in PROSPERO. The UCSF Navigation Guide has registered several of its systematic reviews on chemicals in PROSPERO.
Use of scoring to evaluate individual study quality is wholly inappropriate and inconsistent with best practices in systematic review. As noted in the systematic review approach document, "EPA/OPPT developed a numerical scoring system to inform the characterization of the data/information sources during the data integration phase" (p. 30). Best practices in systematic review expressly discourage the use of scoring to rate individual studies. The Cochrane handbook for systematic reviews of interventions states: The use of scales for assessing quality or risk of bias is explicitly discouraged in Cochrane reviews. While the approach offers appealing simplicity, it is not supported by empirical evidence (Emerson 1990, Schulz 1995b). Calculating a summary score inevitably involves assigning 'weights' to different items in the scale, and it is difficult to justify the weights assigned. Furthermore, scales have been shown to be unreliable assessments of validity (Jüni 1999) and they are less likely to be transparent to users of the review. It is preferable to use simple approaches for assessing validity that can be fully reported (i.e. how each trial was rated on each criterion). (emphases added) [similar excepts from IOM and NAS follow]
Despite these warnings [excerpts from Cochrane, IOM, IRIS] and explicit recommendations against applying scores and weights to study evaluation, OPPT has chosen to employ this strategy. Further, EPA has done this without providing any empirical evidence or scientific justification for why such a deviation from best practices in systematic review is reasonable, necessary, and valid. In reality, scientific justification for study scoring in a systematic review framework is scientifically unsound and does not exist.
The method by which EPA calculates a study's overall quality score highlights the arbitrary nature of the proposed scoring approach. [description of overall score cutoff] The choice of this particular cutoff structure is not science-based. Under this methodology, a study that scores 1.7 is equally weighted relative to a study that scores 2.3, despite the fact that the study with a score of 1.7 was only 0.1 away from being considered a High quality study, whereas the study scoring 2.3 was 0.1 from being considered Low quality. EPA's process amounts to nothing more than an algorithmic exercise lacking any empirical basis.

69	EDF		1	Systematic Review	N/A
70	EDF		1	Systematic Review	N/A
71	EDF		1	Systematic Review	N/A
72	EDF		1	Systematic Review	N/A
73	EDF		1	Systematic Review	N/A

In addition, collapsing all of a study's individual data quality metrics into a single overall study score presents significant challenges. For example, studies for which many criteria are not applicable can receive higher scores than studies that have more applicable criteria, even if they score the same in overlapping metrics. For instance, EPA gives an example on page 50 of a study within only one domain containing two metrics, "Verification or Plausibility of Results" and "QSAR Models," with weighted metric scores of 2 and 1, respectively, which contribute to an overall study score of 1.5. It is reasonable to assume that another study might also have weighted scores of 2 and 1 for the same two metrics, but in addition might have another separate metric that must be scored. If this additional metric has a weighted score of 2, then this second study will receive a lower score than the first study, despite the fact that they have identical scores on their shared metrics. This means that the presence of a third relevant metric is effectively discounting the scores of the other two metrics, despite the fact that the metrics are not related.
In applying a scoring methodology to study evaluation, EPA is not only deviating from best practices in systematic review, it is deviating from the strategies applied by sources that EPA used to develop this document including IRIS and OHAT. In line with best practices in systematic review, neither of these sources uses a numerical scoring approach to rate study quality. Thus, the very sources that EPA cites as resources used to develop its study evaluation approach explicitly state that they do not employ a scoring strategy and yet, EPA has chosen to develop a scoring methodology, without explanation or science-based justification. We strongly urge the agency to do away with a scoring approach to evaluating study quality.
OPPT's approach to weighting criteria is inconsistent with best practices in systematic review; lacks empirical evidence and justification; and is entirely arbitrary. As part of its scoring methodology, OPPT assigns greater weights to metrics that it deems more important than others. EPA refers to these as "critical metrics." However, in its 2014 review of the IRIS program, the NAS wrote that "there is no empirical basis for weighting the different criteria in the scores." OPPT's metric weights imply that the agency has some scientific basis for the degree to which a given metric criteria affects overall study quality. However, the reality is that there is no evidence to support this approach, while there is empirical evidence suggesting that quality scores and weighting lack validity, can be misleading, and introduce bias.
Disregarding best practices, OPPT provides vague, substantively empty explanations for why it has assigned greater weight to certain metrics. For example, in assigning weights to data quality metrics for occupational exposure and release data, OPPT states that "EPA used expert judgement to determine the importance of a particular metric relative to others," and that "EPA judged applicability and temporal representativeness to be the most important towards overall confidence, and these two metrics were determined to be twice as important as other metrics (weighting factors assigned a value of 2)." EPA's "explanation" amounts to arbitrary, subjective judgment and is particularly dubious because EPA has not interrogated its methodology in practice.
EPA states that "the weighting approach for some of the strategies may need to be adjusted as OPPT tests the evaluation method with different types of studies." This statement highlights the arbitrary nature of the weighting factors, and more broadly, the outright dismissal of basic tenets of systematic review. In effect, EPA is explicitly allowing a pathway for bias in its study evaluation approach, as the agency will be able to retrospectively favor some study metrics over others and adjust their weights as the results of the study evaluation process unfold—an approach that is antithetical to developing a science-based, systematic review framework.

74	EDF	1	Systematic Review	p.27, 34
75	EDF	1	Systematic Review	N/A
76	EDF	1	Systematic Review	p. 31

The TSCA systematic review document suggests problematic use of expert judgment. OPPT indicates that expert judgment will be applied throughout its systematic review process:"Professional judgment will be used at every step of the process and will be applied transparently, clearly documented, and to the extent possible, follow principles and procedures that are articulated prior to conducting the assessment (U.S. EPA, 2016)." While expert judgment is certainly part of systematic review, EPA's proposed application of expert judgment raises some concerns. Most notably, the document states that expert judgment may overrule the overall study score that has been developed through the systematic review process: "After the overall score is applied to determine an overall quality level, professional judgment may be used to adjust the quality level obtained by the weighted score calculation." (p. 34) OPPT states that "the reviewer must have a compelling reason to invoke the adjustment of the overall score and written justification must be provided," yet few details are given. For example, it is not clear what qualifies as a "compelling reason" to alter the quality score or whose professional judgment can overrule. While we object to OPPT's use of a scoring methodology to evaluate studies, if there exist legitimate, science-based circumstances that merit changes to a study's "confidence level," they should be factored into the TSCA systematic review document and individual protocols to the extent possible. Further, EPA must, as it has indicated it will do, identify and provide written justification for any adjustment made to overall evaluations of study quality.
OPPT's TSCA Systematic Review document incorrectly and inappropriately conflates study reporting with study quality. In doing, EPA severely jeopardizes use of best available science and weight of the scientific evidence, as the effect of EPA's approach would be to score studies as "low quality" or even exclude studies on the basis of reporting deficiencies rather than actual study quality. Study reporting pertains to how well study authors describe various aspects of their research, including its design and findings. A well-reported study can be of poor quality and a high-quality study can be insufficiently reported. [explanation of risk of bias and quality] Best practices in systematic review strongly advise against conflating issues of reporting and other aspects of study quality when assessing individual studies. While there are some differences across leading systematic review approaches for chemical assessment with how to address reporting issues, its distinction and separation from study quality is clear. [excerpts from the OHAT Systematic Review Handbood, IRIS Draft chloroform assessment protocol, navigation guide, and STROBE statement]
In its TSCA Systematic Review document, OPPT acknowledges the need to delineate between reporting and study quality. "Reporting quality is an important aspect of a study that needs to be considered in the evaluation process. The challenge, in many cases, is to distinguish a deficit in reporting from a problem in the underlying methodological quality of the data/information source. (p. 31)" However, OPPT then chooses an approach that deviates from this established best practice. "The TSCA evaluation strategies incorporate reporting criteria within the existing domains rather than adding a separate reporting domain as recommended in some evaluation tools/frameworks." (p. 31)" OPPT supports this decision to evaluate these metrics in parallel by stating that the aim of its approach is to "assesses reporting and methodological quality simultaneously with the idea of untangling reporting from study conduct while the reviewer is assessing a particular metric for each domain." Even on its face, this explanation is incoherent: how does assessing the two qualities "simultaneously" lead to a reviewer "untangling" the two? This approach seems likely to achieve precisely the opposite of one of its stated goals.

77	EDF	1	Systematic Review	N/A
78	EDF	1	Systematic Review	N/A
79	EDF	1	Systematic Review	N/A
80	EDF	1	Systematic Review	NA
81	EDF	1	Systematic Review	p. 105
82	EDF	1	Systematic Review	N/A

EPA's decision to conflate reporting issues with study quality and comingle their consideration is significant: It could well lead the agency to not use the best available science and not apply a legitimate weight of the scientific evidence approach. For example, OPPT's scoring methodology contains, for each data quality evaluation domain, a set of "serious flaws" that cause a study to be excluded from further consideration in the review. The methodology includes instances in which reporting issues are considered fatal flaws. One of the fatal flaws for monitoring data from studies on consumer, general population and environmental exposure is that "geographic location is not reported, discussed, or referenced." (p. 99) This is inappropriate as relevant monitoring data may not be associated with a specific geographic location. For example, a consumer market survey that examines product-purchasing behaviors may be useful as proxy for estimating exposure even though it may not include location as a data field or may not publish location information in order to protect respondent privacy. The collected information could very well still be useful in ascertaining chemical exposures. Similarly, a study involving biomonitoring of children at several different childcare facilities would likely not specify the geographic location of the facilities for privacy reasons. Yet again, this information could be incredibly valuable in assessing exposure-response relationships.
Even more egregious is the profusion of reporting quality in metrics used to evaluate epidemiological studies. Insufficiencies in reporting by themselves will frequently result in data quality metric scores of low or even unacceptable. For example, absence of STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) checklist items in epidemiological studies result in a metric score of unacceptable for metrics 2, 3, 4, 6, and 7, and a score of low in metric 15. A score of unacceptable in a single metric across any study quality domain will result in the exclusion of an entire study. This is wholly inconsistent with best practices in systematic review, departs from best available science, and would likely result in EPA not using reasonably available information. It also makes clear that EPA has not meaningfully, if at all, tested its systematic review approach, because if it had it would have found a number of high quality, epidemiological studies would be inappropriately excluded.
OPPT's TSCA systematic review document is fraught with problematic metric criteria that do not support the use of best available science. Limited time to comment has prevented an exhaustive review of all metric criteria, but below we highlight some of the problematic metric criteria identified thus far.
Lack of access to underlying study data will downgrade a study's score or eliminate it entirely from consideration. For some of OPPT's data quality metrics, a study must provide underlying data in order to receive a score of "High" or even be considered. Such a standard mirrors the extensive concerns raised by EPA's Strengthening Transparency in Regulatory Science proposed rule, a hugely problematic and widely criticized proposal. As with conflating reporting quality with study quality (see comment section 7), EPA erroneously conflates access to underlying data with study quality—a deeply misguided and misleading treatment of scientific evidence.
Example: For studies on consumer, general population, and environmental exposures to receive a score of "High" in Domain 3 (Accessibility/Clarity), Metric 8 (Reporting of Results), it must meet the following standard: "Supplementary or raw data (i.e., individual data points) are reported, allowing summary statistics to be calculated or reproduced." (p. 105) If the supplementary or raw data are not reported, a study's score is automatically downgraded, regardless of its quality.
Example: For a human epidemiological study to receive a score of "High" in Domain 4 (Potential confounding/variable control), Metric 14 (Reproducibility of analyses), it must meet the following standard: "The description of the analysis is sufficient to understand precisely what has been done and to be reproducible." If an epidemiological study does not meet this standard, EPA will give it a score of "Low."

83	EDF		1	Systematic Review	N/A
84	EDF		1	Systematic Review	p. 76
85	EDF		1	Systematic Review	p.76
86	EDF		1	Systematic Review	p. 77, 103, 110

EPA's invoking of "reproducibility" as a standard to receive a score of "High" in these metrics mirrors similar language in the EPA's censored science proposal, raising serious concerns about the extent to which EPA is effectively requiring that all underlying study data be made publicly available to be meaningfully considered. Also see comments in section 3.A regarding EPA's use of "replicability" as a "verification" standard. EDF incorporates by reference comments submitted by EDF on EPA's proposed rule, Strengthening Transparency in Regulatory Science.
The scoring system also makes clear that OPPT intends to exclude occupational exposure scenarios that are outside the scope of the risk evaluation. For occupational exposure and release data, Domain 2 (Representative), Metric 3 (Applicability) notes that the following will cause a study to be scored "Unacceptable": "The data are from an occupational or non-occupational scenario that does not apply to any occupational scenario within the scope of the risk evaluation." (p. 76)
When EPA discovers studies of occupational or non-occupational scenarios that EPA failed to identify at the scoping stage, EPA must consider whether it needs to revise its approach to the risk evaluation by broadening the scope. TSCA orders EPA to consider "available" and "reasonably available" information in crafting a risk evaluation, and if EPA discovers reasonably available information that reveals the existence of real-world occupational scenarios that EPA failed to identify earlier in the process, TSCA does not authorize EPA to simply ignore that information by labelling the information "unacceptable." Rather, the appropriate resolution is for EPA to consider whether EPA needs to expand the scope to address these real-world exposures. In most circumstances, those circumstances are now "known" to occur and EPA must analyze these known conditions of use.
OPPT's scoring scheme includes data quality metrics that are scored "low" when study data are more than a certain number of years old, but EPA has provided no evidence that older information is per se less informative. For example, it appears that EPA intends to give monitoring data studies a low ranking for the temporal representativeness metric if their data are more than 15 or 20 years old. See p.77, 103, 110. While EPA provides a cursory explanation that older information is allegedly less representative than more recent information, EPA has not provided any empirical evidence supporting this weighting scheme. The temporal representativeness metric that is applied to monitoring data from studies of occupational exposure and release highlights the arbitrary nature of OPPT's scoring approach. To receive a "High" confidence level for this metric, the data must have been collected "after the most recent permissible exposure limit (PEL) establishment or update or are generally, no more than 10 years old, whichever is shorter." (p. 77) To receive a "Medium" score, the data must meet the following requirement: "The monitoring data were collected after the most recent PEL establishment or update but are generally more than 10 years old. If no PEL is established, the data are more than 10 years but generally, no more than 20 years old." And finally, the metric is scored "Low" if the data "were collected before the most recent PEL establishment or update or are more than 20 years old if no PEL is established." There is no empirical basis for favoring data that is fewer than 10 years old more than data that is 20 years old, nor does OPPT even attempt to provide a justification for this distinction. This scoring criteria implies that 9 year-old data is just as valid as 2 year-old data, but is more valid than 11 year-old data. Furthermore, OPPT provides no clarification for how this metric will be applied. Will studies that are 10 years old at the time of the literature search be included in the systematic review, even if those studies are 11 years old during the data evaluation and data integration phases of the review? For longitudinal studies with multiple years' worth of data, will all of the data – or just the most recent year's data – need to fall within the stated time constraints of a given confidence level? These questions underscore the arbitrariness of the data quality criteria that OPPT's data evaluation strategy employs.

87	EDF	1	Systematic Review	p. 245
88	EDF	1	Systematic Review	p.35
89	EDF	1	Systematic Review	p.131

EPA inappropriately applies an adverse outcome pathway (AOP) standard to effect biomarkers in epidemiological studies. For epidemiological studies, Domain 6 (Other (if applicable) Considerations for Biomarker Selection and Measurement), Metric 17 (Effect biomarker (detection/measurement/information biases)) to receive a score of "High" an effect biomarker must be a "[b]ioindicator of a key event in an AOP." (p. 245) To receive a score of "Medium" "[b]iomarkers of effect [must be] shown to have a relationship to health outcomes using well validated methods, but the mechanisms of action is not understood." It is wholly inappropriate to downgrade a study involving biomarkers just because the adverse outcome pathway for an observed effect is unknown. For many chemicals, the biological processes underlying observed effects are not well understood or may not be understood at all. This is the case even for pharmaceuticals available on the market today. The National Research Council wrote in its 2014 report, Review of EPA's Integrated Risk Information System (IRIS) Process, that "if FDA were required to organize drug safety around mechanism, it would be nearly impossible to regulate many important drugs because the mechanism is often not understood, even for drugs that have been studied extensively."
The TSCA systematic review document risks discounting non-guideline studies. OPPT claims that its scoring methodology is not meant to systematically favor guideline studies over non-guideline studies. In some cases, reference to study guidelines (in addition to professional judgement) may be helpful in determining the adequacy or appropriateness of certain study designs or analytical methods. This should not be construed to imply that non-guideline studies necessarily have lower confidence than guideline studies. [p. 35] However, this statement is in itself contradictory. If OPPT is using study guidelines to determine the adequacy and appropriateness of study methods, then guideline studies are likely to receive the highest scores for these data quality metrics because that feature – adherence to a guideline – is used to define the criteria. On the other hand, non-guideline studies, which are more likely to deviate from these standards, will necessarily receive lower scores for these metrics.
Additionally, there are several instances in which the language of the data quality metrics suggests that guideline studies could consistently receive higher scores than non-guideline studies. For example, for experimental data derived from studies on consumer, general population, and environmental exposure (Appendix E), to receive a score of "High" in Domain 1 (Reliability), Metric 1 (Sampling Methodology and Conditions), a study must meet the following standard: -Samples were collected according to publicly available SOPs, methods, protocols, or test guidelines that are scientifically sound and widely accepted from a source generally known to use sound methods and/or approaches such as EPA, NIST, ASTM, ISO, and ACGIH. OR -The sampling protocol used was not a publicly available SOP from a source generally known to use sound methods and/or approaches, but the sampling methodology is clear, appropriate (i.e., scientifically sound), and similar to widely accepted protocols for the chemical and media of interest. All pertinent sampling information is provided in the data source or companion source. (p. 131, emphasis added) Thus, a study must either follow standard protocols or its methods must be similar to standard guidelines for the study to receive the highest score for this metric. This could systematically favor guideline studies over non-guideline studies.

90	EDF	1	Systematic Review	p. 215, 219
91	EDF	1	Systematic Review	p.33
92	EDF	1	Systematic Review	p.23, 24, 26

Similarly, the data evaluation criteria for in vitro toxicity studies (Appendix G) include language that suggests guideline studies would consistently receive higher scores than non-guideline studies. To receive a score of “High” in Domain 4 (Test Model), Metric 15 (Number per group), a study must satisfy the following requirement: “The number of organisms or tissues per study group and/or number of replicates per study group were reported and were appropriate for the study type and outcome analysis, and consistent with studies of the same or similar type.” (p. 215, emphasis added) Here, “appropriate” directs the reader to current standards and guidelines developed by OECD, EPA, and FDA.52 On the other hand, a study would receive a score of “Medium” for this metric if it meets the following description: -The number of organisms or tissues per study group and/or replicates per study group were reported but were lower than the typical number used in studies of the same or similar type (e.g., 3 replicates/strain of bacteria in bacterial reverse mutation assay), but were sufficient for analysis and unlikely to have a substantial impact on results. (p. 215, emphasis added) Here, the basis for scoring a study as “Medium” rather than “High” is that the study did not use a standard methodology. However, to be scored a “Medium,” that discrepancy cannot have affected the results significantly. This means that a study that does not use guideline methods is scored lower, despite the fact that the deviation from established methods has not affected the study’s results. This would appear to systematically favor guideline studies over non-guideline studies. Similar language is found in Domain 7 (Data Presentation and Analysis), Metric 23 (Data interpretation). (p. 219)
One of the confidence levels that can be given to data quality metrics for any study type is “Not rated/applicable.” This category includes instances in which “studies cite a literature source for their test methodology instead of providing detailed descriptions.” (p. 33) Reviewers will only look at this cited literature source if the study under consideration “is not [otherwise] classified as ‘unacceptable’ during the initial review” based on an evaluation of all other data quality metrics. Given that many of OPPT’s data quality metrics focus on reporting quality (which in itself is problematic, as discussed at length in comment section 7), it is reasonable to assume that a study could score “unacceptable” based on reporting issues when, in fact, the information of interest is detailed in another information source referenced by the study authors. Rather than using a “Not rated/applicable” placeholder when a study cites a literature source for its methodology, OPPT should seek out, integrate, and consider all reasonably available information as part of evaluating study quality.
OPPT notes that “one screener conducted the screening and categorization of titles and abstracts.” (p. 24). This is inconsistent with best practices in systematic review, which recommend at least two individuals for all screening steps in order to minimize potential reviewer bias and ensure that all relevant data and studies are captured. As the IOM writes in its standards for systematic review in healthcare, “Without two screeners, SRs may miss relevant data that might affect conclusions about the effectiveness of an intervention. Edwards and colleagues (2002), for example, found that using two reviewers may reduce the likelihood that relevant studies are discarded.” OPPT acknowledges the discrepancy between its approach and best practices in a footnote, stating that a lack of time and resources limited the office to one screener during the title/abstract screening step for the first ten chemicals. However, lack of time and/or resources is not a valid justification for failing to meet systematic review standards that empirically reduce risk of bias. Additionally, OPPT notes that the plan for future reviews is that, “Each article is generally screened by two independent reviewers using specialized web-based software.” (p. 23, emphasis added) Similarly, for the data evaluation step OPPT states that, “Ideally, each data/information source will be screened by two reviewers, but one reviewer may be used.” (p. 26). The use of two or more independent reviewers for each step of the screening process is not a standard that should be applied generally or only when OPPT can meet ideal targets, it is one that OPPT should adhere to without exception.

93	EDF	1	Systematic Review	N/A
94	EDF	1	Systematic Review	p.21
95	EDF	1	Systematic Review	N/A

Absent from the TSCA systematic review document is any consideration of the effect of financial conflict of interest on study results. Empirical evidence reveals that financial conflict of interest held by study authors or sponsors can influence study results. Leading systematic review organizations recognize and incorporate an evaluation of financial conflict of interest at some point in the systematic review process. [excerpt from Cochrane] Indeed, leading scientific journals increasingly require conflict-of-interest disclosures for manuscripts, recognizing the need to have such transparency. These increasingly required publication disclosures facilitate EPA's ability to collect and assess the potential impact conflicts of interest have on study results. EPA has chosen not to collect such information in its systematic review approach. While EDF opposes conflating reporting issues with study quality, it is worth noting the conspicuous omission from data quality metrics for epidemiological studies of STROBE checklist item #22, "Give the source of funding looking and the role of the funders for the present study and, if applicable, for the original study on which the present article is based. At a minimum, we recommend EPA apply OHAT's approach to considering potential impacts of conflicts of interest on individual studies and the body of evidence. [excerpt from OHAT]
EPA makes a troubling, and potentially inaccurate, assertion about the CBI status of health and safety information in the TSCA systematic review document. the Data Collection section of the document EPA states: "EPA/OPPT also plans to search its internal databases for data and information submitted under TSCA (e.g., unpublished industry data). EPA will consider these data in the risk evaluations where relevant and whether or not they are claimed as confidential business information (CBI). If data/information are CBI, EPA/OPPT plans to use it in a manner that protects the confidentiality of the information from public disclosure." Under TSCA section 14(b)(2), health and safety studies and associated information are not eligible for protection from disclosure as CBI (subject to two narrow exceptions). 15 U.S.C. § 2613(b)(2). As with any other health and safety information, such information developed on chemicals to support the development of risk evaluations should be made publicly available. Health and safety information is not eligible under the law for CBI protection unless it would disclose process or mixture-portionality information. Also, EPA must generally scrutinize CBI claims to ensure that they are valid and substantiated per the requirements set out in TSCA section 14, and make its confidentiality determinations publicly available, see 15 U.S.C. § 2625(j)(1). The information referenced in the above quotes from the TSCA systematic review document clearly encompasses "health and safety studies" under TSCA's broad definition of that phrase, TSCA section 14(b)(2), as codified in EPA's regulations at 40 C.F.R. section 716.3. EPA must make this information public. See, e.g., 40 C.F.R. § 720.90(a) ("EPA will deny any claim of confidentiality with respect to information included in a health and safety study" except in limited circumstances).
OPPT must subject the TSCA systematic review document to peer review by established experts in the field given 1) the substantial digression from best practices in systematic review; 2) EPA's decision not to adopt leading systematic review approaches for chemical assessment that have been peer reviewed and developed in consultation with systematic review experts; and 3) the significant uncertainty associated with the outcome of applying its approach, including the implications for risk determination. OPPT must ensure its general approach to protocol development and data integration is included as part of such peer review.

96	UCSP PRHE	1	Systematic Review	N/A
97	UCSP PRHE	1	Systematic Review	N/A
98	UCSP PRHE	1	Systematic Review	N/A
99	UCSP PRHE	1	Systematic Review	N/A
100	UCSP PRHE	1	Systematic Review	N/A

EPA's systematic review framework under TSCA establishes EPA's "rules" for assembling and interpreting the scientific evidence on chemicals in commerce. These "rules" will determine, whether explicitly, implicitly, and/or by default, what evidence EPA will consider, and how it will evaluate that evidence when it is making decisions about potentially hazardous chemicals in commerce. Exposure to industrial, commercial, and consumer product chemicals is ubiquitous from the time of conception until death. As such, EPA's rules for gathering and interpreting the science that evaluates the relationship between these exposures and adverse health effects are of profound importance to the general public, and will have even greater impact on the potentially exposed or susceptible sub-populations Congress explicitly mandated EPA to protect: pregnant women, children, individuals with underlying health conditions, workers, and those with greater exposure and/or greater vulnerability to chemical toxicity and exposure. With so much at stake, we are deeply concerned by EPA's ad hoc and incomplete TSCA systematic review framework, which is inconsistent with current, established, best available empirical methods for systematic review. Moreover, as we detail below, the application of EPA's TSCA framework would likely result in the exclusion of quality research from EPA's decision-making. Accordingly, the TSCA systematic review method does not meet the mandate of the law to use the "best available science."
Based on the most current empirically demonstrated principles of systematic review methods, we provide EPA with concrete recommendations and approaches to correct its methodology and inform timely science-based decision-making to achieve the Agency's mission of protecting the public from harmful chemicals. [Summary comments are followed by detailed comments]
EPA's TSCA systematic review framework is ad hoc, incomplete, and does not follow established methods for systematic review that are based on the best available science. We recommend: EPA should implement a systematic review method that is compatible with empirically based existing methods and aligns with the Institute of Medicine'se definition of a systematic review, including but not limited to, using explicit and pre-specified scientific methods for every step of the review. EPA should consider methods demonstrated for use in environmental health, and which have been endorsed and utilized by the National Academy of Sciences, i.e., the National Toxicology's Office of Heath Assessment and Translation systematic review method, and the Navigation Guide Systematic Review Method. EPA's TSCA systematic review framework should be peer-reviewed by qualified external experts in the field.
EPA's TSCA systematic review framework utilizes a quantitative scoring method that is incompatible with the best available science in fundamental ways: a. Quantitative scores for assessing the quality of an individual study are arbitrary and not science-based; the Cochrane Collaboration and National Academy of Sciences recommend against such scoring methods. b. EPA's scoring method wrongly conflates how well a study is reported with how well the underlying research was conducted; and c. EPA's scoring method excludes research based on one single reporting or methodological limitation. We recommend: EPA should not use a quantitative scoring method to assess quality in individual studies; it should not conflate study reporting with study quality; and it should not exclude otherwise quality research based on a single reporting or methodological limitation. Rather EPA should employ a scientifically valid method to assess risk of bias of individual studies.
EPA's TSCA systematic review framework does not consider financial conflicts of interest as a potential source of bias in research. We recommend: EPA should assess study and author funding source as a risk of bias domain for individual studies.

101	UCSP PRHE		1	Systematic Review	N/A
102	UCSP PRHE		1	Systematic Review	N/A
103	UCSP PRHE		1	Systematic Review	N/A
104	UCSP PRHE		1	Systematic Review	p. 15
105	UCSP PRHE		1	Systematic Review	p. 15
106	UCSP PRHE		1	Systematic Review	N/A

The literature review step of EPA's TSCA systematic review framework incorporates select best practices, but also falls short of, or is unclear about, many other best practices for conducting a systematic and transparent literature review. We recommend: EPA should make its framework for conducting a literature review congruent with all of the Institute of Medicine's best practices and explicitly include rules for when the list of relevant studies will be considered final.
EPA's TSCA systematic review framework correctly recognizes that mechanistic data are not required for a hazard assessment, but EPA is not clear that these data, if available, can only be used to increase, and not to decrease, confidence in a body of evidence. We recommend: EPA should be explicit that mechanistic data can only be used to upgrade a hazard classification, or increase the confidence of a finding made based on evaluation of animal and human data, and that these data will not be used to decrease confidence in a body of evidence.
EPA's TSCA systematic review framework is not independent of the regulatory end user of the review. We recommend: EPA's TSCA systematic reviews should be produced independently of the regulatory end user of the review.
EPA's TSCA systematic review framework is ad hoc, incomplete, and does not follow established methods for systematic review that are based on the best available science. The best available scientific method for a systematic review (SR) specifies that all components of a review be established in a publically available protocol written prior to conducting the review to minimize bias and to ensure transparency in decision-making. For example, the Institute of Medicine defines a systematic review as a "scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies" (emphasis added) (16)(p.1). A fatal flaw in EPA's SR framework is that it lacks essential SR elements, including but not limited to: (1) a protocol for executing a SR developed prior to conducting the SR; (2) an explicit method for evaluating the overall body of each evidence stream, i.e., animal, human, etc.; and (3) an explicit method for integrating two or more streams of evidence, including defined criteria for the type and level of evidence needed for a decision by EPA. Notably, EPA's TSCA SR Framework presents a diagram of a complete SR framework in Figure 3-1 (page 15) and states in footnote 4 on that page that the: Diagram depicts systematic review process to guide the first ten TSCA risk evaluations. It is anticipated that the same basic process will be used to guide future risk evaluations with some potential refinements reflecting efficiencies and other adjustments adopted as EPA/OPPT gains experience in implementing systematic review methods and/or approaches to support risk evaluations within statutory deadlines (e.g., aspects of protocol development would be better defined prior to starting scoping/problem formulation).
However, EPA's TSCA SR Framework then proceeds to describe an ad hoc and highly flawed method limited to only the data collection and, to a limited extent, the data evaluation components of a SR. Specifically, Figure S-1 below, excerpted from the National Academy of Sciences 2014 review of the EPA IRIS program's systematic review method (17), presents all of the components of a science-based SR. The red box indicates the parts of a SR method that EPA has included in its proposed framework. [Figure S-1 Systematic review in the context of the IRIS process is depicted with a red box around the Identify Evidence and Evaluate Studies]
EPA's piecemeal approach is not only in direct contradiction with the best available scientific methods for SR, but also incompatible with the regulatory definition off "weight of evidence" in the risk evaluation rule, which specifies a complete method spelled out in a protocol developed before conducting the review. Therefore, the TSCA systematic review method violates both TSCA statute and regulation.

107	UCSP PRHE	1	Systematic Review	p. 8, 9
108	UCSP PRHE	1	Systematic Review	p. 9

EPA explicitly states that it is proceeding with its first ten risk assessments in the absence of a pre-defined protocol and a complete method for systematic review. (p. 9) ... the purpose of the document is internal guidance that ... sets out general principles to guide EPA's application of systematic review in the risk evaluation process for the first ten chemicals ... EPA had limited ability to develop a protocol document detailing the systematic review approaches and/or methods prior to the initiation of the risk evaluation process for the first ten chemical substances. For these reasons, the protocol development is staged in phases while conducting the assessment work" (emphasis added). Additional details on the approach for the evidence synthesis and integration will be included with the publication of the draft TSCA risk evaluations." In effect, EPA is saying it does not have time to comply with its regulatory requirement to conduct a science-based systematic review, and will not actually develop its protocol until it completes the first ten systematic reviews. First, this approach is in clear violation with scientifically-validated approaches to conducting systematic reviews. In its review of the EPA's Integrated Risk Information System (IRIS) program's proposed SR methods, the National Academy of Sciences specified that, "Completing the literature search as part of protocol development is inconsistent with current best practices for systematic review, and the IRIS program is encouraged to complete the public-comment process and finalize the protocol before initiating the systematic review" (15)(Pg. 8). In the case of TSCA risk assessments, EPA is not only completing the literature search as part of protocol development, it is completing the entire systematic review in the absence of a protocol and complete method. It is blatantly biased to write the rules of evidence assembly and interpretation at the same time one is applying the rules, and as such, this method cannot be validly referred to as a science-based systematic review.
Second, a lack of time is not a credible rationale for EPA's failure to conduct a science-based systematic review for the first ten TSCA chemicals. There are multiple well-developed, science-based, peer-reviewed and validated methods for conducting systematic reviews in environmental health that EPA could readily apply, including the SR method and handbook developed by the Office of Health Assessment and Translation at the National Toxicology Program, and the Navigation Guide Systematic Review Method, which has been demonstrated in six case studies. The National Academy of Sciences cited both of these SR methods as exemplary of the type of methods EPA should use in hazard and risk assessment. Further, the National Academy of Sciences utilized both methods in its 2017 assessment of the potential health impacts of endocrine active environmental chemicals. Specifically, in its 2017 review the National Academy of Sciences found: "The two approaches [OHAT and Navigation Guide] are very similar ... and they are based on the same established methodology for the conduct of systematic review and evidence assessment (e.g., Cochrane Collaboration, AHRQ Evidence-based Practice Center Program, and GRADE). Both the OHAT and Navigation Guide methods include the key steps recommended by a previous National Academies committee (NRC 2014) for problem formulation, protocol development, specifying a study question, developing PECO statement, identifying and selecting the evidence, evaluating the evidence, and integrating the evidence" (19)(page 119)." Protocols developed for applying the Navigation Guide and the OHAT method have been published and can serve as a template to further expedite EPA's TSCA reviews.

109	UCSP PRHE	1	Systematic Review	p.26
110	UCSP PRHE	1	Systematic Review	p.35
111	UCSP PRHE	1	Systematic Review	N/A
112	UCSP PRHE	1	Systematic Review	N/A
113	UCSP PRHE	1	Systematic Review	p. 33, 225

Furthermore, the language of EPA's systematic review framework is confusing, contradictory, and poorly and incorrectly referenced with little science or policy foundation. This suggests the authors of EPA's TSCA Systematic Review Framework lack sufficient understanding of the scientific process integral to this work. A particularly egregious example is EPA's stated understanding of EPA's TSCA statutory science standards: "(Pg. 26) EPA/OPPT is required by TSCA to use the weight of the scientific evidence in TSCA risk evaluations. Application of weight of evidence analysis is an integrative and interpretive process that considers both data/information in favor (e.g., positive study) or against (e.g., negative study) a given hypothesis within the context of the assessment question(s) being evaluated in the risk evaluation." This directly contradicts EPA's own published rule which defines what a systematic review is (see footnote "e", above) and such an understanding completely subverts the purpose of a systematic review which is to explicitly avoid a simplistic analysis that would led to erroneous conclusions along the lines of stating that, for instance, "five studies are in favor (positive) and ten are against (negative) and therefore the weight is … ".
Another bewildering statement by EPA concerns its highly quantitative scoring method, which is the main topic of its systematic review framework (see comment #2, below). EPA adds a caveat to the scoring method that says quantitative scoring is actually a qualitative method, and further: "The [scoring] system is not intended to imply precision and/or accuracy of the scoring results" (Pg. 35).
The ad hoc and incomplete nature of EPA's systematic review framework is incompatible in many additional fundamental ways, described further in detail below, with science based methods of systematic review developed, endorsed, and/or advanced by the: National Academy of Sciences; the Institute of Medicine; the National Toxicology Program; the Cochrane Collaboration; the Grading of Recommendations Assessment, Development and Evaluation (GRADE) method; the international scientific collaboration that developed a framework for the "systematic review and integrated assessment" (SYRINA) of endocrine disrupting chemicals; the SYRCLE systematic review method for animal studies; the Campbell Collaboration's methods; and the Navigation Guide systematic review method developed by a collaboration of scientists led by the University of California San Francisco. Most of these organizations also pre-publish their protocols either online (i.e., the National Toxicology Program) or in PROSPERO (i.e., UCSF).
We recommend: EPA should implement a systematic review method that is compatible with empirically based existing methods and aligns with the Institute of Medicine's definition of a systematic review, including, but not limited to, using explicit and pre-specified scientific methods for every step of the review. EPA should consider methods demonstrated for use in environmental health, and which have been endorsed and utilized by the National Academy of Sciences, i.e., the National Toxicology's Office of Heath Assessment and Translation systematic review method, and the Navigation Guide Systematic Review Method. EPA's TSCA systematic review framework should be peer-reviewed by qualified external experts in the field.
Quantitative scores for assessing the quality of an individual study are arbitrary and not science-based. EPA's SR framework employs a quantitative scoring method to assess the quality of individual studies, assigning, based on its "professional judgment", various weights for quality domains and then summing up the quantitative scores to decide whether a study is of "high", "medium", or "low" quality [description of numberical scoring method and cut-off values] This overall scoring method is applied to all streams of evidence, and our comments reflect our objection to EPA's applying scoring to any and all streams of evidence. Illustrative of the scoring method, in Appendix H "Data Quality Criteria for Epidemiologic Studies," (page225) EPA presents how scoring is further applied to human studies, explaining: [description of critical metrics]

114	UCSP PRHE	1	Systematic Review	p.225
115	UCSP PRHE	1	Systematic Review	N/A
116	UCSP PRHE	1	Systematic Review	N/A

There is no scientific evidence to support EPA's selection of these "critical metrics" as being more important that other metrics, i.e., why within the "study participation" domain "selection" and "attrition" are more important than "comparison group"; and there are no data supporting EPA's choice of particular numbers for weighting these 'critical metrics' (i.e., some metrics are "twice" as important as the other metrics). Overall, there is no scientific justification for EPA to assign these or any other quantitative scoring measures for assessing the quality of an individual study. The implicit assumption in quantitative scoring methods is that we know empirically how much each risk of bias domain contributes to study quality, and that these domains are independent of each other. This is not a scientifically supportable underlying assumption. Research has documented that scoring methods have, at best, unknown validity, may contain invalid items, and that results of a quality score are not scientifically meaningful or predictive of the quality of studies. An examination of the application of quality scores in meta-analysis found that quality-score weighting produced biased effect estimates, with the authors explaining that quality is not a singular dimension that is additive, but that it is possibly non-additive and non-linear. Aggregating across quality criteria to produce a single score is recognized by preeminent systematic review methodologists as problematic and unreliable because the weights assigned are arbitrary and focus on the quality of reporting rather than the design and conduct of the research. Scoring is not utilized by empirically based systematic review methodologies, such as the Cochrane Collaboration or GRADE. As stated by the Institute of Medicine, "... systematic review teams have moved away from scoring systems to assess the quality of individual studies toward a focus on the components of quality and risk of bias".
The Cochrane Collaboration, founded in 1993, is an international non-profit and independent organization that produces and disseminates systematic reviews of healthcare interventions and is a key locus of the world's most authoritative expertise on systematic review methods. Cochrane's methodology states: "The current standard in evaluation of clinical research calls for reporting each component of the assessment tool separately and not calculating an overall numeric score (emphasis added)" The National Academy of Sciences in its review of the EPA's IRIS program's method for SR, strongly supported a methodology that did not incorporate quantitative scoring, stating "... Cochrane discourages using a numerical scale because calculating a score involves choosing a weighting for the subcomponents, and such scaling generally is nearly impossible to justify (Juni et al. 1999). Furthermore, a study might be well designed to eliminate bias, but because the study failed to report details in the publication under review, it will receive a low score. Most scoring systems mix criteria that assess risk of bias and reporting. However, there is no empirical basis for weighting the different criteria in the scores. Reliability and validity of the scores often are not measured. Furthermore, quality scores have been shown to be invalid for assessing risk of bias in clinical research (Juni et al. 1999). The current standard in evaluation of clinical research calls for reporting each component of the assessment tool separately and not calculating an overall numeric score (Higgins and Green 2008).
EPA's scoring method wrongly conflates how well a study is reported with how well the underlying research was conducted. Study reporting addresses how well research findings are written up, i.e., whether there is a complete and transparent description of what was planned, what was done, what was found, and what the results mean. Guidelines and checklists for authors have been developed to help ensure all information pertinent to assessing the quality and meaning of research is included in the report. The "Strengthening of Reporting of Observational Studies in Epidemiology" or "STROBE" Initiative is an example of a checklist of items that should be included in articles reporting such research.

117	UCSP PRHE	1	Systematic Review	p.31
118	UCSP PRHE	1	Systematic Review	N/A

EPA's SR Framework uses reporting measures in its scoring of the quality of human studies, including incorporating reporting guidelines into the reasons for scoring studies "low quality" (Metrics 1 and 15) or "unacceptable for use" (Metrics 2, 3, 4, 6, 7). EPA's SR Framework acknowledges that reporting is not the same as an underlying flaw in study methodology (Pg. 31), but then proceeds to ignore this distinction by using reporting as a measure of the quality of the underlying research. EPA's SR Framework not only does not "untangle" reporting from quality, it specifically conflates the two by using metrics in the STROBE reporting guidelines to score individual studies. The authors of the STROBE guidelines specifically note the guidelines are not a measure of the quality of the underlying research, stating: "The STROBE Statement is a checklist of items that should be addressed in articles reporting on the 3 main study designs of analytical epidemiology: cohort, case control, and cross-sectional studies. The intention is solely to provide guidance on how to report observational research well; these recommendations are not prescriptions for designing or conducting studies. Also, while clarity of reporting is a prerequisite to evaluation, the checklist is not an instrument to evaluate the quality of observational research (emphasis added). ... Our intention is to explain how to report research well, not how research should be done. We offer a detailed explanation for each checklist item. Each explanation is preceded by an example of what we consider transparent reporting. This does not mean that the study from which the example was taken was uniformly well reported or well done; nor does it mean that its findings were reliable, in the sense that they were later confirmed by others: it only means that this particular item was well reported in that study."

The Cochrane Collaboration Handbook for conducting a SR clearly distinguishes reporting and bias, the latter which is defined as "a systematic error, or deviation from the truth, in results or inferences" (20). The Cochrane Manual for conducting systematic reviews is explicit about not conflating reporting with bias, stating: "Bias may be distinguished from quality. The phrase 'assessment of methodological quality' has been used extensively in the context of systematic review methods to refer to the critical appraisal of included studies. The term suggests an investigation of the extent to which study authors conducted their research to the highest possible standards. This Handbook draws a distinction between assessment of methodological quality and assessment of risk of bias, and recommends a focus on the latter. The reasons for this distinction include:

1. The key consideration in a Cochrane review is the extent to which results of included studies should be believed. Assessing risk of bias targets this question squarely.
2. A study may be performed to the highest possible standards yet still have an important risk of bias. For example, in many situations it is impractical or impossible to blind participants or study personnel to intervention group. It is inappropriately judgemental to describe all such studies as of 'low quality', but that does not mean they are free of bias resulting from knowledge of intervention status.
3. Some markers of quality in medical research, such as obtaining ethical approval, performing a sample size calculation and reporting a study in line with the CONSORT Statement (Moher 2001d), are unlikely to have direct implications for risk of bias.
4. An emphasis on risk of bias overcomes ambiguity between the quality of reporting and the quality of the underlying research (although does not overcome the problem of having to rely on reports to assess the underlying research)."

119	UCSP PRHE	1	Systematic Review	N/A
120	UCSP PRHE	1	Systematic Review	p.227
121	UCSP PRHE	1	Systematic Review	N/A

Importantly, in the application of EPA's SR Framework, studies can be scored as "low quality," and even excluded from EPA's review, based solely on a deficiency in reporting, irrespective of the quality of the underlying research. Research documents that important information is often missing or unclear in published research, as word limits, styles, and other specifications are highly variable, and non-standardized among peer-reviewed journals. As such, efforts to improve reporting are focused on uptake of reporting guidelines by journal editors and researchers. Improving reporting is needed in academic research, but as stated by the developers of the STROBE guidelines, "We want to provide guidance on how to report observational research well. ... the checklist is not an instrument to evaluate the quality of observational research." Given the historical and present-day deficiencies in how studies are reported in the peer-reviewed literature, and because EPA's scoring system rates as 'unacceptable for use' any human study that does not report even one of five reporting metrics, EPA's proposal could reasonably be expected to lead to the exclusion from EPA's consideration much of the existing body of knowledge on the impact of environmental chemicals on human health, and is inconsistent with TSCA mandates to use the "best available science" and "reasonably available information." Applying flawed exclusion criteria that directly contradicts widely accepted empirically based SR methodological approaches will almost certainly result in flawed conclusions and threaten the protection of the public's health.

EPA's scoring method excludes research based on one single reporting or methodological limitation. In the "fatal flaw" component of EPA's SR Framework's scoring system, for each type of evidence stream, i.e., epidemiologic, animal, in vitro, etc., EPA created an arbitrary list of metrics that make studies "unacceptable for use in the hazard assessment," stating: EPA/OPPT plans to use data with an overall quality level of High, Medium, or Low confidence to quantitatively or qualitatively support the risk evaluations, but does not plan to use data rated as Unacceptable. Studies with any single metric scored as 4 will be automatically assigned an overall quality score of Unacceptable and further evaluation of the remaining metrics is not necessary (emphasis added). An Unacceptable score means that serious flaws are noted in the domain metric that consequently make the data unusable (or invalid)" (Pg. 227). There is no empirical basis for EPA's selected list of fatal flaws. Illustrative of this "fatal flaw" aspect of EPA' scoring system, for human epidemiologic studies (See Section H.5, Table H-8 (page 231), EPA lists six domains of study quality, i.e., study participation; exposure characterization; outcome assessment; potential confounding/variable control; analysis; and other considerations for biomarker selection and measurement, and 19 metrics to assess the six domains. A study that has even one of the 19 "serious flaws" metrics is considered to be "unacceptable for use."

EPA's list of "serious flaws" are not all equal indicators of study quality: For example, among human observational studies, any one of the list of 19 metrics can eliminate a study from consideration as EPA considers all of these "flaws" to be of equal import; as described in detail above, such weighting is arbitrary and not a science-based method.

122	UCSP PRHE	1	Systematic Review	p. 243
123	UCSP PRHE	1	Systematic Review	N/A
124	UCSP PRHE	1	Systematic Review	N/A
125	UCSP PRHE	1	Systematic Review	N/A

EPA's list of "serious flaws" are not all related to real flaws in the underlying research. Reporting guidelines are wrongly equated with "serious flaws" in study quality. Reporting guidelines are wrongly equated with "serious flaws" in study quality. For example, in scoring the quality of human studies, 5 of 19 "serious flaw" metrics (Table H-8) are STROBE reporting guidelines (STROBE checklist items # 6,7,8,13,15). A study would be scored as "unacceptable for use" by EPA based on any one of these STROBE reporting guidelines. As described above in comment #2a, the STROBE guideline developers explicitly state this is neither the intended nor a scientifically valid use of these guidelines. Analysis is equated with a "serious flaw" in study quality, but statistical power alone is not a valid measure of study quality. For example, EPA's framework excludes human studies that do not meet EPA's criteria for "high" in the analysis domain. EPA does not state how it will calculate whether a study is "adequately" powered. According to EPA's framework, to be included in an EPA review, a study must meet the "high" criteria in EPA's "Metric 13, Statistical power (sensitivity, reporting bias)" as presented in the box below. Studies that are not "high" quality for this metric would be designated as "unacceptable for use" by EPA: [excerpt from EPA Metric 13, Table H-9, p. 243]
First and foremost, EPA provides no method for how it will determine the "adequacy" of the statistical power of a study on which to base its score, and provides no rationale for excluding studies with less than 80% statistical power. According to STROBE guideline developers, ... "before a study is conducted power calculations are made with many assumptions that once a study is underway may be upended; further, power calculations are most often not reported"
EPA's Metric 13 statistical power/sensitivity also appears to confuse bias with imprecision. Individual studies that are "underpowered" (for example, because in the real world the exposed population may not be large enough for statistical purposes even if they are health impacted) can still be potentially valuable to science-based decision-making. For example a small study may be imprecise but that should not be confused with whether it is biased (20); a small study can be imprecise but at the same time less biased than a larger study (17). Small "underpowered" studies can also be combined in a meta-analysis that increases the statistical power of the body of evidence to reflect the relationship between an exposure and a health impact. Additionally, "underpowered" studies that find a health effect to be present may be indicative of a larger effect size than anticipated. Thus, omitting such studies would severely bias the conclusions of the review.
Illustrative of how EPA's "analysis" metric could result in excluding high quality research that can inform science-based decision-making by EPA, in a 2017 systematic review by Lam et al. "Developmental PBDE Exposure and IQ/ADHD in Childhood: A Systematic Review and Meta-analysis," none of the 4 high-qualityp studies included in the meta-analysis reported a power calculation, and yet together, these studies found "a 10-fold increase (in other words, times 10) in PBDE exposure associated with a decrement of 3.70 IQ points (95% confidence interval:0.83,6.56)." It is also notable that one of the studies in the meta-analysis, Herbstman et al. 2010, was assessed by the review authors to be "probably high risk of bias" for "Incomplete Outcome Data." As such, this otherwise high quality study, i.e., all of the other domains were "definitely" or "probably" low risk of bias, would meet EPA's criteria for "unacceptable for use" based on STROBE reporting guideline #15, "Report numbers of outcome events or summary measures over time". In short, the Lam et al systematic review, using the best available scientific methods, found that a ubiquitous environmental contaminant is impacting human intelligence, a finding that was subsequently reviewed and endorsed by the National Academy of Sciences. Yet EPA's SR review framework would exclude crucial pieces of this body of evidence based on the Agency's inaccurate, non-science-based criteria for deeming studies 'unacceptable.' This is contrary to TSCA's mandate to use the best available science.

126	UCSP PRHE	1	Systematic Review	N/A
127	UCSP PRHE	1	Systematic Review	N/A
128	UCSP PRHE	1	Systematic Review	N/A

Level of exposure is equated with a "serious flaw". EPA's "exposure characterization" domain for human studies includes the level of exposure as a fatal flaw, stating: "For all study types: The levels of exposure are not sufficient or adequate (as defined above) t to detect an effect of exposure (Cooper et al., 2016)." Unlike human experimental studies, which are largely precluded for ethical reasons, human observational studies can only be based on what exposures actually occur in the real world. EPA offers no explanation of how one could know whether the levels would be "sufficient or adequate" enough to detect an effect. Given the vagaries of this metric, it could be reasonably anticipated that it would permit EPA to arbitrarily exclude quality research from its decision-making. We recommend: EPA should not use a quantitative scoring method to assess quality in individual studies; it should not conflate study reporting with study quality; and it should not exclude otherwise quality research based on a single reporting or methodological limitation. Rather EPA should employ a scientifically valid method to assess risk of bias of individual studies.
EPA's TSCA systematic review framework does not consider financial conflicts of interest as a potential source of bias in research. As observed by the Deputy Editor (West) of JAMA in 2010, "the biggest threat to [scientific] integrity [is] financial conflicts of interest". Yet EPA's systematic review framework is silent on how it will take into account this empirically documented influence on the results of scientific research. Underscoring this EPA SR framework deficiency is the fact that recent studies empirically document that industry sponsorship produces research that is favorable to the sponsor. The influence of financial ties on research can be traced to a variety of types of biases, and this conflict of interest needs to be distinguished from non-financial interests in the research, which can also affect research. The fact that funding source needs to be accounted for in some manner is empirically supported and not a subject of scientific debate; what scientists differ on is how to best address funding as a potential source of bias; for example, whether funding source is assessed as a specific risk of bias domain or considered at multiple points in the evaluation. For example, funding source is recommended as a factor to consider when evaluating risk of bias of individual studies for selective reporting, and then again for evaluating the body of evidence for publication bias, and/or to be considered as a potential factor to explain apparent inconsistency within a body of evidence. A 2017 Cochrane systematic review of industry sponsorship and research outcome concluded … "industry sponsorship should be treated as bias-inducing and industry bias should be treated as a separate domain". The National Academy of Sciences in its review of the EPA IRIS program's SR method found that "Funding sources should be considered in the risk-of-bias assessment conducted for systematic reviews that are part of an IRIS assessment (p 79).
Notably, EPA's exclusion of consideration of funding source and other potential conflicts of interests is also internally inconsistent with EPA's own improper reliance on STROBE guidelines as quality measures: STROBE guidelines item #22 specified that "the source of funding and the role of funders, could be addressed in an appendix or in the methods section of the article". Importantly, including funding as a risk of bias as a domain does not mean excluding industry sponsored studies from EPA's hazard and risk assessment; it only means documenting funding as one of many domains of potential bias and evaluating its impact on the overall quality of the body of evidence. We recommend: EPA should assess study and author funding source as a risk of bias domain for individual studies.

129	UCSP PRHE	1	Systematic Review	N/A
130	UCSP PRHE	1	Systematic Review	N/A
131	UCSP PRHE	1	Systematic Review	N/A

The literature review step of EPA's TSCA systematic review framework incorporates select best practices, but also falls short of, or is unclear about, many other best practices for conducting a systematic and transparent literature review. Overall, we commend the EPA for its efforts to incorporate many best practices for a comprehensive literature search in its systematic review framework. We compared EPA's framework for systematic review to the Institute of Medicine's (IOM's) best practices for the literature review step of a systematic review(See IOM 2011 Chapter 3. and TABLE E-1), which was applied by the National Academy of Sciences in its review of EPA's IRIS Program methods for systematic review (See Table 4-1 Pp. 43-55). We found EPA's framework to be consistent with 12 of IOM's 27 best practices for conducting a literature search (Figure 1 and Appendix 1). There are two key features of EPA's framework that are clearly inconsistent with IOM's best practices. EPA fails: (1) to include or exclude studies based on the protocol's pre-specified criteria, a practice that is critical to avoiding results-based decisions; and (2) to use two or more members of the review team, working independently, to screen and select studies, which is an essential quality-assurance measure. For the remaining 13 IOM best practices, EPA's framework is either unclearly stated (N=7) or the practice is not mentioned at all (N=6). However, based on the literature review methods presented in the First Ten TSCA Risk Evaluations, EPA's framework appears to have incorporated six additional best practices that are either unclear or not mentioned in EPA's SR framework: (1) work with a librarian or other information specialist trained in performing systematic reviews to plan the search strategy (IOM 3.1.1); (2) Design the search strategy to address each key research question (IOM 3.1.2); (3) Search regional bibliographic databases if other databases are unlikely to provide all relevant evidence (IOM 3.1.9); (4) Conduct a web search (IOM 3.2.5); and (5) Provide a line-by-line description of the search strategy, including the date of search for each database, web browser, etc. (IOM 3.4.1).
EPA should make its framework for conducting a literature review transparently congruent with all of IOM's best practices. This includes addressing two critical inconsistencies: (1) include or exclude studies based on the protocol's pre-specified criteria to prevent results-based decisions; and (2) Use two or more members of the review team, working independently, to screen and select studies, to ensure quality assurance. The transparency of the framework would be improved by specifying how EPA is addressing each best practice; at this juncture, how EPA intends to specifically handle many components of its literature searches could not readily be identified.
For example, the framework is unclear about whether EPA will include papers published in languages other than English. The exclusive reliance on English-language studies may lead to under-representation of the entire body of available evidence, and studies have also suggested that language bias might lead to erroneous conclusions. Furthermore, when considering the inclusion or update of an existing systematic review, studies have found that language-inclusive systematic reviews (including studies in languages other than English) were of the highest quality, compared with other types of reviews. Online translation tools are readily available to allow screeners to quickly evaluate study abstracts for relevance, and therefore we recommend EPA to incorporate non-English language studies in their screening and not simply exclude in advance these potentially relevant papers.

132	UCSP PRHE	1	Systematic Review	N/A
133	UCSP PRHE	1	Systematic Review	p.172
134	UCSP PRHE	1	Systematic Review	p.172
135	UCSP PRHE	1	Systematic Review	N/A

Additionally, EPA's framework should explicitly include rules for determining when the list of relevant studies will be considered final i.e., "stopping rules." Newer scientific studies will inevitably continue to appear in scientific journals and it will be impossible to continually attempt to include all these studies in a chemical assessment. To meet the deadlines as mandated by the Lautenberg Amendments, EPA should state clear stopping rules in the form of deadlines or criteria for when the body of included relevant studies will be finalized for the purposes of the chemicals assessment. We also strongly encourage EPA in its stated exploration of automation and machine learning tools, which can help speed the production of EPA's systematic reviews. We recommend: EPA should make its framework for conducting a literature review congruent with all of the Institute of Medicine's best practices, and explicitly include rules for when the list of relevant studies will be considered final.
EPA's TSCA systematic review framework correctly recognizes that mechanistic data are not required for a hazard assessment, but EPA is not clear that these data, if available, can only be used to increase, and not to decrease, confidence in a body of evidence. EPA's TSCA framework (page 172) states that EPA will use the evaluation strategies for animal and in vitro toxicity data to assess the quality of mechanistic and pharmacokinetic data supporting the model, and may tailor its criteria further to evaluate new approach methodologies (NAMs). We agree with EPA that mechanistic data need to be evaluated in a manner comparable to how other streams of evidence are evaluated. Data generated by alternative test methods (such as high-throughput screening methods) are not different than any other type of in vitro or cell-based assay data that would be considered in a systematic review. These kinds of assays provide mechanistic data. However, in this case, as described in comment # 2 above, EPA's use of its evaluation strategies for animal and in vitro toxicity data would entail using a quantitative scoring method that is incompatible with the best available science in fundamental ways. EPA should employ a scientifically valid method to assess risk of bias of individual studies in all streams of evidence, including mechanistic data.
EPA's framework (page 172) states, "the availability of a fully elucidated mode of action (MOA) or adverse outcome pathway (AOP) is not required to conduct the human health hazard assessment for a given chemical (emphasis added)." We strongly agree with EPA that mechanistic data are not needed for a hazard assessment. In addition, EPA's framework should be explicit that mechanistic data are only used to increase confidence in a hazard assessment, and never to decrease confidence.
The National Academy of Sciences explicitly considered how mechanistic data could be utilized in a systematic review for evidence integration (19). The committee came to two conclusions. First, the same protocol for evaluating relevance and study quality must be used with mechanistic data as for any other study. For example, in the report's case study on phthalates, the committee was not able to integrate results from high-throughput assays because the cell lines used were of unknown relevance to the in vivo mechanism of phthalate toxicity (19)(pg.78). Second, the foundation of the hazard classification in a systematic review is the animal and human data, with the mechanistic data playing a supporting role. If mechanistic data is relevant, it can be used to upgrade a hazard classification, or increase the confidence of a finding made based on evaluation of animal and human data. A hazard classification is never made based on high-throughput or other kinds of mechanistic data alone(Pp. 158-9). We recommend: EPA should be explicit that mechanistic data can only be used to upgrade a hazard classification, or increase the confidence of a finding made based on evaluation of animal and human data, and that these data will not be used to decrease confidence in a body of evidence.

136	UCSP PRHE	1	Systematic Review	N/A
137	UCSF_CommentJune252018	2	Systematic Review, General	3
138	UCSF_CommentJune252018	2	Systematic Review, General	3
139	UCSF_CommentJune252018	2	Systematic Review, General	3

EPA's TSCA systematic review framework is not independent of the regulatory end user of the review. EPA's TSCA systematic review/risk assessment process is not independent of the TSCA risk management process, a conflict that is incompatible with best scientific methods. EPA's SR framework was developed and is being implemented by the Office of Chemical Safety and Pollution Prevention (OCSPP), which is also responsible for regulating the environmental exposures under TSCA review. In contrast, other EPA chemical assessment programs such as the IRIS program are intentionally placed in a non-regulatory research arm (the Office of Research and Development), to create separation from the Agency's program office responsible for regulatory decisions. This separation supports IRIS's ability to develop impartial chemical toxicity information independent of its ultimate use by EPA's program and regional office in risk assessment and risk management decisions. The National Academy of Sciences supported this in its 2018 report, stating that: "Current best practices [for systematic reviews in other medical disciplines] recommended by the Institute of Medicine (IOM 2011) suggest that the IRIS teams involved in the systematic-review process should be independent of those involved in regulatory decision-making who use the products of the systematic-review teams (emphasis added)". This same principle should also be implemented across the Agency and specifically for TSCA assessments. We recommend: EPA's systematic reviews should be produced independently of the regulatory end user of the review.
1. EPA should improve its literature search and systematic review strategies to strengthen its evaluations and increase transparency. Overall, we strongly commend the EPA for its efforts to utilize a systematic and transparent method of research synthesis to reach a concise, strength of evidence conclusion about the human health hazard resulting from exposures to these ten chemicals. Efforts to integrate systematic review methods, including the explicit development of search terms, strategies, and inclusion/exclusion criteria beforehand, is relatively new in EPA's chemical assessment and as such, we applaud the EPA for this and its general improvements in its hazard assessment methodology. These scoping documents generally provide an important infrastructure for outlining EPA's screening approach for identifying relevant references and to document decisions made in the process of identifying the body of scientific literature that will be evaluated in the chemical assessments. To improve on this document and advance EPA's uptake of systematic review methods of research synthesis, we identify the following opportunities for improvement.
EPA should not exclude studies based on language. EPA's search strategy is limited to English-only studies. The exclusive reliance on English-language studies may not represent the entire body of available evidence, and studies have suggested that language bias might lead to erroneous conclusions. Furthermore, when considering the inclusion or update of an existing systematic review, studies have found that language-inclusive systematic reviews (including studies in languages other than English) were of the highest quality, compared with other types of reviews. Online translation tools are readily available to allow screeners to quickly evaluate study abstracts for relevance, and therefore we recommend EPA to incorporate non-English language studies in their screening and not simply exclude these potentially relevant papers.
EPA should provide exclusion reasons for off topic citations. In the Bibliography Supplemental File for the Scope Documents, EPA has provided lists of bibliographic citations that were identified and screened from the initial literature search and the initial categorization of whether citations were on topic or off topic. We recommend EPA additionally provide exclusion reasons that were used to come to the conclusion that each citation was off topic, as this is a standard recommendation to fulfill transparency in documenting and reporting all decisions made in the study selection process. This is particularly important as EPA has proposed to do its screening in Distiller, proprietary software that presumably will not be made publicly available, raising concerns regarding the transparency and reproducibility of this screening step.

140	UCSF_CommentJune252018	2	Systematic Review	3
141	UCSF_CommentJune252018	2	Systematic Review	3
142	UCSF_CommentJune252018	2	Systematic Review, General	3
143	UCSF_CommentJune252018	3	Systematic Review	3
144	UCSF_CommentJune252018	2	Systematic Review	3

EPA should consider other tools for systematic review. EPA has also proposed to extract data results in the DRAGON software. We strongly encourage EPA to also consider other potential software tools that have been developed and actively incorporated into the process of systematic review, such as Swift Reviewer, Active Screener, HAWC (Health Assessment Workplace Collaborative). These tools will help to ensure consistent and transparent execution and presentation of reviews and increase transparency of EPA assessment. Furthermore, we urge EPA to work with the National Toxicology Program and other organizations involved in these efforts in an ongoing basis to develop these and other open source tools to train scientists in their use. We believe that such infrastructure development will be critical to increasing the efficiency of chemical assessments and to expedite uptake of systematic reviews in environmental health.
EPA should have two independent reviewers for screening steps. EPA has outlined its process for screening title and abstracts of papers as having a single reviewer reviewing papers to determine whether the study is on-topic or off-topic. As part of this process, a senior-level technical expert in the topic area of interest reviewed the appropriateness of the assigned tags for "the first batch of studies" and provided feedback to the screener. Senior-level technicians also provided feedback and guidance on specific references to the individual screeners as needed during the screening and tagging process. From the description of this process, it does not appear that two independent reviewers screen all titles and abstracts for potential inclusion. Using two independent reviewers is a standard approach in systematic reviews and therefore we strongly recommend that EPA include a second independent reviewer within this process to ensure that all studies are screened by two reviewers at each step (title and abstract and full text).
EPA should clearly document decisions related to the identification and search. For example, it was unclear how many studies were included in the first batch of studies reviewed by the senior-level technician—these decisions should be clearly specified beforehand as to the number (or percent) that will be reviewed by this independent reviewer. Furthermore, it is unclear how many studies the senior-level technical experts are reviewing generally as to their additional feedback and guidance to individual screeners. This should be more clearly stated and described beforehand in these protocols. We recommend EPA broaden the set of studies that are initially screened in the first batch to ensure consistency across reviewers and demonstrated understanding of protocol instructions by all reviewers before moving on to screening the remaining records. It is stated in the Gray Literature Search Results that individual screeners would screen and tag 10 references that would be then independently reviewed by the senior-level technical expert. However, this does not seem to be an adequate number of studies as it is a small number relative to the expected number of records that will ultimately be screened.
EPA should clarify how it will handle discrepancies in the inclusion/exclusion and tagging process. As it is stated in its current protocol, it appears that the senior-level technical expert has the final say in determining the final inclusion/exclusion decision and tagging, for the subset of studies they evaluate. However, this should be clarified and we also highly recommend that a third party reviewer be incorporated as an arbiter for these decisions if consensus cannot be reached between the two reviewers, as is typically standard in systematic reviews.
EPA should stratify its exclusion criteria separately at the title and abstract and full-text screening steps. It is likely that title and abstracts of papers would not contain sufficient detail to evaluate all exclusion criteria—many of these would likely only be identified in the full-text of the paper. To increase the efficiency of the screening process, it would help to create a subset of exclusion criteria most relevant when screening the title and abstracts of records versus the larger set of exclusion criteria relevant to screening the full text of records.

145	UCSF_CommentJune252018	2	Systematic Review	3
146	UCSF_CommentJune252018	2	Systematic Review	3
147	UCSF_CommentJune252018	2	Systematic Review	3
148	UCSF_CommentJune252018	2	Systematic Review	N/A

EPA should clearly outline the process for handling anticipated overlap with literature relevant to multiple topics. EPA should describe how this will be addressed by the screeners and whether the same reviewer will be responsible for screening papers with inclusion/exclusion criteria across multiple topics or whether different reviewers are responsible only for screening studies for one particular topic. Additional details in regards to the process by which this screening will occur would be helpful. Given the breadth of each assessment (searching literature related to fate, engineering, exposure, human health, and environmental hazard) and the complexity of the screening process (tagging on-topic and off-topic literature and using additional sub-categories or sub-tags to allow for additional categorization), there appears to be the potential for individual papers to fall into different topic categories and have many different tags and sub-tags applied to indicate their relevance. However, it is unclear how this will be organized in the screening phase. Search strategies and inclusion/exclusion criteria appear to have been developed specifically for each literature topic and the potential overlap of literature relevant to multiple topics is not addressed.
EPA should explicitly include stopping rules for when the list of relevant studies will be considered final. There is no discussion of stopping dates or the process of updating the literature search to search for newer studies. Newer scientific studies will inevitably continue to appear in scientific journals and it will be impossible to continually attempt to include all these studies in a chemical assessment. To meet the deadlines as mandated by the Lautenberg Amendments, EPA should state clear stopping rules in the form of deadlines or criteria for when the body of included relevant studies will be finalized for the purposes of the chemicals assessment.
EPA should ensure gray literature search results are adequately screened. EPA's gray literature search strategy proposes to utilize Google's API to develop custom searches and return the first 100 results, sorted by predicted relevancy so that the results likely to be most relevant are screened first. It is unclear why this number is limited to only the first 100 and whether there was an empirical reason for why this particular number was selected. We recommend that EPA ensure that an adequate number of search results are screened, in particular considering that the gray literature can contribute potentially important information relevant to toxicity, mode of action, exposure, fate and transport, engineering or occupational exposure, or existence of publication bias. EPA should consider "snowball searching," where the citations of included (i.e., on-topic) references are searched as well as using databases such as Web of Science to search for references that cite the included citations. EPA states that it plans on assessing the specificity and efficiency of the literature searches, through comparison of references either cited in existing problem formulation and risk assessment documents, in the public use documents and supporting life cycle diagrams, and comparison of the references cited in review articles. Snowball searching will contribute to the evaluation of the specificity and efficiency of its literature searches, and also help to identify newer relevant studies that could potentially be included that have not yet been indexed in main databases such as PubMed.

EPA should incorporate appropriate tools for updating and evaluating systematic reviews in their chemical assessments. Garner et al., as part of efforts by a Cochrane Collaboration panel for updating guidance for systematic reviews, published guidance in 2016 for determining when it is appropriate to update a systematic review and outlining the steps for performing the update. We have attached this guidance as an Appendix to these comments. EPA should evaluate the Cochrane tool's applicability to environmental chemicals given that Cochrane systematic reviews are geared towards reviews of clinical intervention evidence, so these tools may require updating and tailoring for an application to environmental health data.

149	UCSF_CommentJune252018	2	Systematic Review	N/A
150	UCSF_CommentJune252018	2	Systematic Review	N/A
151	UCSF_CommentJune252018	2	Systematic Review	N/A
152	UCSF_CommentJune252018	2	Systematic Review	N/A
153	UCSF_CommentJune252018	2	Systematic Review	N/A

A recent NAS report recommends EPA should develop policies and procedures to allow the agency to identify, use and update existing systematic reviews. The committee also noted that it was important that the existing systematic review's study question directly addresses EPA's topic of interest and that the methods are critically evaluated before the systematic review is used and updated. EPA should ensure that only the highest quality systematic reviews be considered appropriate for use. It will be critical for EPA to develop tools to assist with the process of evaluating existing systematic reviews, particularly as this field continues to rapidly expand and more systematic reviews relevant to environmental health questions are published in the scientific literature, potentially of variable quality.

One tool which might be helpful for evaluating the risk of bias in systematic reviews is the ROBIS tool, which the NAS committee utilized in their report. This tool was developed using rigorous methodology and can be applied for evaluating internal validity of systematic reviews in conjunction with other available tools to critically appraise and assess their quality. Of particular note is the strong emphasis on the recommendation that tools such as ROBIS should not be used to generate a composite quality score, as it has been well-documented that scoring can lead to bias in evaluation of the studies. As such, the ROBIS tool presents several options for visually and graphically presenting results from risk of bias assessments based on individual domains or the overall rating, enabling reviewers to highlight particular areas of concern or reviews that are most relevant to the target question of interest.

Another tool which may be helpful in this process is the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), used by authors of systematic reviews to improve the reporting of elements relevant to the systematic review and meta-analyses. Increasingly, scientific journals are requiring the inclusion of checklists such as PRISMA with the submission of systematic reviews considered for publication. Although this tool is used to evaluate study reporting, and is not an assessment instrument to gauge the quality of a systematic review, it can still provide a useful framework to identify reported components of an existing systematic review in the process of evaluating quality or to identify missing components requiring follow-up with study authors to obtain additional information.

Furthermore, we strongly encourage EPA to evaluate the potential for financial conflicts of interest as an element in their study design. This is currently included as a consideration in evaluation risks of bias in some frameworks, such as the Navigation Guide, and extracted for consideration as an additional domain in other frameworks, such as that developed by the National Toxicology Program's (NTP) Office of Health Assessment and Translation (OHAT). The Cochrane Collaboration's risk of bias tool does not currently include a specific domain for bias related to study funding source, but this is an area of active discussion among its members. The Cochrane Collaboration has recognized the importance of identifying study funding source, which has been empirically shown to be associated with biases. A recent report from the NRC recommended that the U.S. EPA consider funding sources in their risk of bias assessment conducted for systematic reviews.

We also strongly recommend EPA identify tools that may potentially not be appropriate for human health chemical assessments. Many tools are currently being developed for evaluating risk of bias, quality, and strength of evidence for individual studies as well as for systematic reviews. It is critical that EPA evaluate tools developed in other fields that may be relevant, such as for clinical or preclinical animal or human studies, as these tools could potentially be modified for an application to questions of environmental health relevance. However, these tools should be applied with caution—due to the differences in the types of evidence under evaluation a direct application to a difference evidence base than intended could lead to biased and erroneous conclusions.

154	UCSF_CommentJune252039	2	Systematic Review	N/A
155	UCSF_CommentJune252040	2	Systematic Review	N/A

4. EPA should rely on existing IRIS assessments for hazard identification. Moving forward, EPA should complete hazard identification or add additional studies only through a systematic review process, which integrates animal, human and mechanistic evidence as recommended by the recent NAS report. EPA cites existing IRIS assessments for five chemicals; because these are EPA's own assessments which have gone through the Agency's peer-review process, and in some cases NAS review, EPA can rely on these existing finalized, authoritative assessments for hazard identification. Moving forward, a weight of evidence evaluation is required by law, which EPA defines as: "Weight of scientific evidence means a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance." Therefore, EPA should use a systematic review process for evaluating scientific information for chemicals that do not have an IRIS assessment and for any additional studies that will be considered for the chemicals that have IRIS assessments.
For the scoping document, EPA should include all hazards identified in the literature, and not make decisions about their relevance to the risk evaluation until a systematic review has been completed. For a number of chemicals, EPA has inappropriately drawn conclusions about hazards prior to the completion of a systematic review. Some examples are given in the table below where EPA concludes that HBCD, NMP and pigment violet 29 are not genotoxic based on previous assessments and without conducting a systematic review. Text from table: HBCD: "Available data suggest that HBCD is not genotoxic. Existing assessments have also concluded, based on genotoxicity information and a limited lifetime study, that HBCD is not carcinogenic (NICNAS, 2012; EINECS, 2008; TemaNord, 2008; OECD, 2007). Unless new information indicates otherwise, EPA does not expect to conduct additional in-depth analysis of genotoxicity or cancer hazards in the risk evaluation of HBCD at this time." [p. 36 of Scope] NMP: "NMP is not mutagenic, based on results from bacterial and mammalian in vitro tests and in vivo systems and is not considered to be carcinogenic (RIVM, 2013; OECD, 2007; WHO, 2001). Unless new information indicates otherwise, EPA does not expect to conduct additional in-depth analysis of genotoxicity and cancer hazards in the NMP risk evaluation." [p. 36 of Scope] PV29: "Testing for carcinogenicity of Pigment Violet 29 has not been conducted. However, negative genotoxicity results, structure-activity considerations and the expectation of negligible absorption and uptake of Pigment Violet 29 (based on very low solubility), indicate carcinogenicity of Pigment Violet 29 is unlikely. Unless new information indicates otherwise, EPA does not expect to conduct additional, in-depth analyses of genotoxicity and cancer hazards in the risk evaluation of Pigment Violet." [p. 29 of Scope]

156	UCSF_CommentJune252041	2	Systematic Review	N/A
157	UCSF_CommentJune252042	2	Systematic Review	N/A
158	UCSF_CommentJune252043	2	Systematic Review	N/A

The National Academies recently released a report with recommendations on implementation of systematic review for EPA's chemical evaluations (which we will refer to as the 'NAS Systematic Review report' for simplicity). First, they recommend that EPA should develop policies and procedures that allow the agency to use and update existing systematic reviews, since the committee concluded that could potentially save time and resources. EPA should conduct a review to determine whether there are existing systematic reviews on the topic of interest and if there is, EPA should evaluate it to determine if it is high-quality. The NAS recommends that EPA should build on existing high-quality reviews to incorporate new studies and use the updated systematic review as a basis for its assessment. The assessments cited by EPA to support the hazard identification claims are not systematic reviews; even if they were, EPA should evaluate them for quality before relying on their conclusions.
Second, it is very likely that additional studies have been published since the assessments EPA cites were completed. EPA should develop criteria to evaluate the internal validity (risk of bias) of individual studies, utilizing existing tools that have been developed and empirically demonstrated on environmental health studies such as the Navigation Guide or the OHAT approach. We also recommend that EPA not using a scoring system to evaluate study quality. Specifically, we note that empirically validated approaches in the clinical sciences such as Cochrane discourage using a numerical scale scoring approach for evaluating study quality because calculating a score requires choosing a weighting scheme for each component, which generally is nearly impossible to justify. Furthermore, a study might be well designed to eliminate bias, but because the study failed to report details in the publication under review, it will receive a low score--most available scoring systems include a mix of risk of bias and reporting biases which is inappropriate. Additionally, quality scores have been shown to be invalid for assessing risk of bias in clinical research. The current standard in evaluation of both clinical and environmental health research calls for reporting each component of the assessment tool separately and not calculating an overall numeric score.
Data generated by alternative test methods (such as high-throughput screening methods) are not different than any other type of in vitro or cell-based assay data that would be considered in a systematic review. These kinds of assays provide mechanistic data, and the NAS Systematic Review report explicitly considered how mechanistic data could be utilized in a systematic review for evidence integration. The committee came to two conclusions. First, the same protocol for evaluating relevance and study quality must be used with mechanistic data as for any other study. For example, in the report's case study on phthalates, the committee was not able to integrate results from high-throughput assays because the cell lines used were of unknown relevance to the in vivo mechanism of phthalate toxicity. Second, the foundation of the hazard classification in a systematic review is the animal and human data, with the mechanistic data playing a supporting role. If mechanistic data is relevant, it can be used to upgrade a hazard classification, or increase the confidence of a finding made based on evaluation of animal and human data. A hazard classification is never made based on high-throughput or other kinds of mechanistic data alone.

159	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health	N/A
160	EPA-HQ-OPPT-2016-0737-DRAFT-0113_CEH	1	Systematic Review	N/A
161	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Systematic Review	N/A

More generally, the Office of Pollution Prevention and Toxics (OPPT) has released a guidance document that describes the general systemic review principles it will use to conduct risk evaluations under the amended TSCA. As noted in its risk evaluation rule, EPA has concluded that systematic review is an integral part of a weight of the scientific evidence approach and that integrating systematic review into risk evaluations is critical to meet the statutory requirements of TSCA. In the systematic review, HSIA supports the use of a numerical scoring system to inform the characterization of the data information sources during the data integration phase. We also see as critical the evaluation of data quality prior to incorporation of the information into the risk evaluation. OPPT's systematic review approach should provide an objective platform upon which to address ongoing controversies regarding data quality for key endpoints.
5. The problem formulation must require a validated process for systematic review. The approach to analyzing studies using its own version of a systematic review that EPA has outlined in this Problem Formulation is troubling and inconsistent with current scientific methods. We recommend that EPA adopt either the Systematic Review protocol developed by the National Toxicology Program's Office of Health Assessment and Translation (OHAT) or the SYRINA (systematic review and integrated assessment) framework published in Environmental Health (2016 15:74) The OHAT protocol provides for and "uses a very transparent process to document the basis for scientific judgments." This process ensures a standardized methodology for evaluating scientific studies and provides documentation on how conclusions are reached. The SYRINA protocol "allows for the evaluation and synthesis of evidence from multiple evidence streams" and a decision made using the protocol "regarding regulatory action is not only dependent on the strength of evidence, but also the consequences of action/inaction."
The many shortcomings of the scoping documents and problem formulations are compounded by the June 11 TSCA document for applying "systematic review" methods in the TSCA risk evaluations. As explained in our separate comments on this document, it would require data on the 10 chemicals to be reviewed using an arbitrary set of numerical criteria for study quality that has not been peer reviewed and is in conflict with other systematic review approaches used within EPA and by other federal agencies that have been endorsed by authoritative bodies like the National Academy of Sciences (NAS). Application of the TSCA systematic review document will unjustifiably restrict the body of evidence that informs EPA judgments about risk and hamper the Agency's ability to use the most relevant and meaningful data for decision-making on the 10 chemicals.

162	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy, Systematic Review	N/A
163	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Systematic Review	N/A
164	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Systematic Review, Policy	NA

In the problem formulations themselves, however, EPA outlines a much broader approach. It indicates that all studies on IRIS-assessed chemicals will be reviewed using the "study quality" scoring system in EPA's TSCA systematic review document and other as-yet unidentified protocols for reviewing study relevance and weight.61 This process would necessarily involve revisiting the interpretation of studies already evaluated in IRIS, potentially making different judgments about their quality and relevance and modifying overall IRIS determinations of the "best available science" and "weight of the evidence." Moreover, these judgments would be driven by a deeply flawed and unscientific method for reviewing studies that would result in less defensible conclusions than peer reviewed IRIS assessments. Footnote: 61 Typical is this description of EPA's approach in the problem formulation for asbestos, the subject of a comprehensive IRIS assessment: EPA expects to consider and analyze human health hazards as follows: 1) Included human health studies will be reviewed using the evaluation strategies laid out in the Application of Systematic Review in TSCA Risk Evaluations (U.S. EPA, 2018). • Studies will be evaluated using specific data evaluation criteria. • Study results will be extracted and presented in evidence tables by cancer endpoint. 2) Evaluate the weight of the scientific evidence of human health hazard data. • EPA will rely on the weight of the scientific evidence when evaluating and integrating human health hazard data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence. • Assess dose-response information to refine quantitative unit risk for lung cancer and mesothelioma. Review the appropriate human data identified to update, or reaffirm, the 1988 quantitative estimate of the unit risk of asbestos-related lung cancer and mesothelioma by the inhalation route. 3) In evaluating reasonably available data, EPA will determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.
ACC-CPTD supports the approach to risk evaluation outlined in the draft problem formulation for TCE, particularly in relation to the following – • The general systematic review principles for identifying, selecting, assessing, integrating, and summarizing available hazard and exposure data described by EPA for the development of the TCE risk evaluation under TSCA are consistent with the requirements for the use of the best available science and the weight of scientific evidence outlined in the LCSA
Systematic review has become a standard for data collection, integration, and evaluation in risk assessment. We are encouraged by OPPT's plan to use systematic review in the TSCA evaluation process. However, we note some additional clarifications that are necessary for EPA to move forward. As acknowledged in the Application of Systematic Review in TSCA Risk Evaluations, the guidance for the systematic review process is not yet complete. While we recognize the monumental efforts required to establish the guidance through critical appraisal of individual studies, the guidance does not yet address how information will be integrated. Additionally, ACC/CPTD requests that OPPT more clearly address how previous assessments, searches, or efforts for TCE will be acknowledged, integrated, and/or updated as part of the overall systematic review to support the risk evaluation. Although it is important that OPPT consider these previous efforts, the LCSA requires that the Office conduct its own review in accordance with TSCA and not rely on prior, inadequate assessments.

165	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, Systematic Review	N/A
166	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Systematic Review	N/A
167	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General	N/A

4.0 Existing Assessments of TCE Are Not Consistent with OPPT's Systematic Review Principles or Section 26 of TSCA

As noted in its risk evaluation rulemaking, OPPT has concluded that systematic review is an integral part of a WOE approach and that integrating systematic review into risk evaluations is critical to meet the statutory requirements of TSCA. As transparency is an essential part of any approach to systematic review, OPPT has released guidance outlining the general systematic review principles it will use to conduct risk evaluations under the amended TSCA. The guidance provides a comprehensive description of how it will conduct data searches, screening, extraction, and evaluation and general guidance on how it expects to perform data synthesis and integration. It provides a useful outline of the steps OPPT will use to evaluate study quality – an aspect that has been sorely missing from previous Agency assessments of TCE. The Systematic Review Principles announced by OPPT are the subject of a separate ACC comment and are further discussed below. In brief, we support several aspects of the guidance, including –

• Use of a numerical scoring system to inform the characterization of the data information sources during the data integration phase,
• Use of a weighting approach to reflect that some metrics are more important than others when assessing overall quality of the data,
• Evaluation of the quality and relevance of available studies prior to incorporating the information into a risk evaluation, and
• Disqualification from further consideration studies for which the confidence level of one or more metrics is rated as unacceptable.13

Footnote:
13 In keeping with EPA's proposal to strengthen transparency in regulatory science (83 Fed Reg 18768, April 30, 2018), systematic review should also factor in access to raw data for objectively examining study validity and data analyses that underpin critical toxicity values.

Reviewers have voiced concern about the lack of a well-defined process for selecting and evaluating studies used in IRIS has been voiced by reviewers for over a decade. In its 2011 review of the draft assessment for formaldehyde, the National Research Council (NRC) noted that – " [t]he general problems that the committee identified are not unique to the draft IRIS assessment of formaldehyde. Committees of the Board on Environmental Studies and Toxicology (BEST) of the [NRC] have reviewed a number of IRIS assessments in the last decade, including three . . . in the last 5 years. Some of the general problems identified by the present committee have been commented on by the other BEST committees. For example, the 2006 NRC report on dioxin and related compounds commented on the need for formal, evidence-based approaches for noncancer effects, the need for transparency and clarity in the selection of data sets for analysis, and the need for greater attention to uncertainty and variability. . . The 2010 NRC review of the draft IRIS assessment of tetrachloroethylene found similar problems and provided a chapter, "Moving Beyond the Current State of Practice," that addressed methodologic issues and the failure to establish clear and transparent methods for carrying out and presenting the assessment . . . That report also provided a broad set of recommendations on characterization of uncertainty."

The 2011 NRC report noted that applying standard study quality criteria would improve the transparency and consistency of EPA assessments. The report added that the evaluation and selection of available studies "is related to a fundamental issue of filtering the literature to identify the studies that provide the best dose-response information."

168	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Systematic Review	N/A
169	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Systematic Review	N/A
170	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Systematic Review	N/A
171	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Systematic Review	N/A
172	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, Systematic Review	N/A

The 2011 NRC report noted that applying standard study quality criteria would improve the transparency and consistency of EPA assessments. The report added that the evaluation and selection of available studies "is related to a fundamental issue of filtering the literature to identify the studies that provide the best dose-response information." In its subsequent 2014 review of the IRIS program, NRC observed that "although EPA has identified and is assessing important characteristics of the quality of human and animal studies, it has not historically conducted the assessments in a consistent and standardized way for studies included in IRIS assessments." NRC concluded that – "[e]xperience gained from randomized clinical trials in human and veterinary medicine suggests that systematic reviews that assess animal toxicology studies for quality and risk of bias 17 would improve the quality of IRIS reviews." Footnote: 17 An assessment of study quality evaluates the extent to which the researchers conducted their research to the highest possible standards and how a study is reported. Risk of bias is related to the internal validity of a study and reflects study-design characteristics that can introduce a systematic error (or deviation from the true effect) that might affect the magnitude and even the direction of the apparent effect. (NRC 2014, at 7)
The report further explained that "there is no assessment of the risk of bias in the studies evaluated" in IRIS assessments, nor do they include a "description of quality-assurance measures for the collection of assessment data." Establishment of a transparent, reproducible, and scientifically defensible process for evaluating individual studies is long overdue within the IRIS program. As noted by the NRC –" an IRIS assessment needs to include a transparent evaluation of the risk of bias of studies used by EPA as a primary source of data for the hazard assessment.EPA should specify the empirically based criteria it will use to assess risk of bias for each type of study design in each type of data stream."
NCEA has announced that it will implement systematic review in its assessment practices for future reviews, but has given no indication that any such reviews will be conducted for existing IRIS assessments, like the 2011 assessment for TCE.
Similar concerns about the lack of a systematic review were raised during the peer review of OPPT's Work Plan Assessment for TCE conducted in 2013. In her final comments, the review panel chair notes that "the principal criterion for inclusion/exclusion [in the Work Plan assessment] would be the credibility/integrity of the study rather than simply the route of exposure." The panel chair further reasons – "[i]f the Agency had conducted a systematic review of the literature and each study as it was developing the IRIS document, it would be a relatively easy task to identify the one best data set to represent the endpoint/duration of exposure /(sub)population to be evaluated. But there is not documentation to show that this exercise was carried out. . . . If [the Office of Pollution Prevention and Toxics] didn't do its own systematic review of those . . . studies before using them, in the screening level assessment, it should do it before keeping them in a refined assessment."
8.0 Further Clarification of the Systematic Review Process is Necessary The road map for implementing systematic review for the first ten TSCA risk evaluations (Figure 1-1 in the draft Application of Systematic Review in TSCA Risk Evaluations) provides a summary of the process. We acknowledge that OPPT is using TCE, along with the 9 other initial chemicals, as test chemicals for defining its systematic review process. However, there are several aspects important to the use of systematic review in the overall risk evaluation that are not reflected in the road map or in the TCE Problem Formulation – including how concurrent development of the systematic review process will impact the overall risk evaluation.

173	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Systematic Review	N/A
174	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Systematic Review	N/A
175	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Systematic Review	N/A
176	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Systematic Review	N/A
177	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Systematic Review	N/A

8.1 OPPT Should Clarify How Previous TCE Reviews Will be Used in the Systematic Review As noted in the Application of Systematic Review in TSCA Risk Evaluations, the systematic review process involves a specific order for the conduct of each element of systematic review. Critical to such is the initial problem formulation phase, which, for TCE, has been completed and is the subject of these comments herein, followed by protocol development and subsequent conduct of the review. However, when previous EPA efforts are considered, there appears to be a disordering of the systematic review process that has already occurred for TCE, with the literature search and screening activities presented in the 2017 Scoping Document - prior to the completion of the problem formulation stage. It is unclear, moreover, if the literature review presented in the Scoping Document is representative of the search that would be conducted as part of the systematic review process, or if another search will be conducted.
As part of problem formulation, it is common to rely on authoritative reviews and other reliable secondary sources for scoping, and to conduct initial searches to gauge the volume and nature of the underlying literature as it relates to scoping an assessment for feasibility, resource needs, and timing. However, it is not within the guidance provided by the Institute of Medicine or in OHAT 2015 to complete a comprehensive literature review prior to, or as part of, problem formulation. OPPT should more clearly address how previous assessments, searches, or efforts for TCE will be acknowledged, integrated, and/or updated as part of the overall systematic review supporting the risk evaluation.
8.2 The Review Protocol for TCE Should be Made Available for Public Comment Also unclear and seemingly not in compliance with standard systematic review procedures is the absence of a protocol established for the review to support the TCE risk evaluation. Notably, the Problem Formulation addresses many standard elements of a protocol (e.g., PECO, inclusion/exclusion criteria), but is not documented and presented as such. It does however, make a single reference to a protocol - “The protocol describes how studies will be evaluated using specific data evaluation criteria and a predetermined systematic approach.” No other information is provided regarding a protocol for TCE. To comply with systematic review standards (IOM, 2011; OHAT, 2015), including those described in the Application of Systematic Review in TSCA Risk Evaluations (e.g., Figure 3-1), OPPT should differentiate problem formulation and protocol development and provide an opportunity for public comment specifically on the protocol for TCE. Alternatively, and at a minimum, OPPT should clarify its plans for generating a protocol for TCE.
8.3 The Public Should Have an Opportunity to Comment on Evidence Integration Approaches before They are Applied to TCE As acknowledged in the Application of Systematic Review in TSCA Risk Evaluations, the guidance for the systematic review process is not yet complete. While we recognize the monumental efforts required to establish the guidance through critical appraisal of individual studies, the guidance does not yet address how information will be integrated. This is a significant issue as it represents the most difficult and complex part of a systematic review, providing the structure to combine findings of studies with assessment of data quality and confidence in the body of evidence as related to the risk evaluation. The evidence integration component of the systematic review guidance should be completed and issued for public comment prior to formal application to TCE (or any other chemical).
9.0 Clarifications and Uncertainties in the Systematic Review Approach Upon reviewing the “Application of Systematic Review in TSCA Risk Evaluations” in context of information in the TCE Problem Formulation, ACC/CPTD would like to provide the following comments in the further improvement and development of these two documents:

178	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Systematic Review	N/A
179	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Systematic Review	N/A
180	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Systematic Review	N/A

9.1 Data Quality Criteria Should be Categorized for Both Internal and External Validity We commend the efforts to transparently and rigorously evaluate study quality. In particular, the level of detail for each study type and guidance on how to interpret each metric criteria clearly represents significant effort and forethought. This approach allows for a more standardized, comprehensive, and transparent evaluation. Further, OPPT has included study quality elements beyond just those commonly associated with internal validity or risk of bias – a decision which will help facilitate a more complete assessment of data quality and is also commended. In order to aid in integration and development of conclusions, it is recommended that the study quality criteria should be categorized by internal and external validity. That is, by study quality elements related to risk of bias for internal validity (i.e., those that provide a measure of whether the design and conduct of a study compromised the credibility of the link between exposure and outcome) and those elements related to external validity or generalizability (i.e., those related to fit-for-purpose, relevance, and reliability as it relates to a given endpoint or outcome). Such a categorization of data quality elements could be achieved by restructuring the tables. Numerical scores or categories for both internal and external validity could also be considered separately.
In practice, it is difficult to apply domain-based appraisal criteria (some of which are included in the data quality tables) across study types due the variability in study design and objectives of toxicological studies. This is particularly important when considering the diversity of experimental animal toxicology studies designed to assess specific endpoints. Criteria for appraising the quality are likely to vary between, for example, a developmental study relative to a sensitization study. Similarly, the interpretation of compliance with a given criteria is also likely to vary based on study type. That is, there are methodological aspects unique to each type of study or topic that are often important to consider. This is highlighted by the diversity of methods associated with, for example, OECD guideline studies for various endpoints. Topic-specific refinement for appraising the quality of human studies is also important. One example of how this is important relative to the draft systematic review guidance is as follows: • Data quality criteria for Metric 9 (Domain 4) – Covariate Adjustment (confounding). Scoring and determination of serious flaws are all dependent on assessing if appropriate adjustments or considerations were made for "primary covariates (excluding co-exposures) and confounders." No further guidance, however, is provided on how such covariates will be identified as "primary." While there are some covariates that may be important in most all studies (e.g., smoking status), the "primary" covariates are more often unique to a specific topic. For example, in evaluating reproductive and developmental effects, alcohol consumption is a well-established covariate. As described in Wikoff et al., only one study was controlled for alcohol consumption in the TCE evidence base on FCM (and this single study also reported that this covariate was significant on its own, highlighting the importance of the covariate). Thus, in an assessment of TCE, it would be important to identify alcohol consumption as a "primary covariate" – yet neither the systematic review guidance nor the TCE Problem Formulation suggest that there will be any topic refinement to allow for such.
Further, there are likely to be instances in which there are methodological aspects important to the chemical under evaluation (e.g., complexities in conducting research due to low solubility or high volatility) that should be accommodated in assessing validity.

181	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Systematic Review	2.4.2
182	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Systematic Review	N/A
183	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Systematic Review	N/A

184
185
186

Because of the recognized heterogeneity within toxicological evidence bases (which include studies in humans), topic-specific refinement of study quality criteria are required. Thus, while ACC/CPTD supports the generation of criteria specific to human, animal, and in vitro studies, OPPT should also further clarify "intra-stream" application of the study quality criteria for the experimental animal studies as it relates to the diversity of endpoints48 that will be evaluated as well as refinements specific to the agent under evaluation. As part of the plans to modify the criteria based on internal experience and external feedback, OPPT should address the likely need for topic-specific refinements in these various capacities, and also describe when and how the refinements will be made and applied. Footnote: 48 Table G-1 lists the various types of animal studies (lethality, irritation, sensitization, reproduction, fertility, developmental, neurotoxicity, carcinogenicity, systemic toxicity, metabolism, pharmacokinetics, absorption, immunotoxicity, genotoxicity, mutagenicity, and endocrine disruption) for data quality.
9.3 Clarification is Required to Ensure Consistency in Scoring The guidance provided in the Data Quality Criteria description tables (e.g., Table G-14) helps analysts in scoring a study for a particular metric. However, the information in these guidance tables is generally not of sufficient detail to ensure consistency among analysts or between assessments. Two examples from the evaluation of study quality for animal studies are provided for illustrative purposes: • Data quality criteria for Metric 6 – Randomized allocation of animals: As currently stated, studies that report a flawed method would get a medium or low score, but those that simply report that randomization without the method used could receive a high score. OPPT should provide clarification on how to score studies that report animal randomization but do not report the method of randomization. It would make sense to follow OHAT's guidelines and also score such studies "low" for this metric, but at the very least, OPPT should provide further guidance on scoring this metric. • Data quality criteria for Metric 9 – Reporting of dose/concentrations: The serious flaw listed for Metric 9 is for a study that is lacking data reported to verify reported dose/ concentrations. However, criteria scores 1 or 2 for Metric 9 do not indicate such data are required, rather that the dose/concentrations are clearly reported (i.e., "without ambiguity"), or that information is reported that would allow the dose/concentrations to be calculated by readers. One could assume the intent in the serious flaw description is for a study that hasn't already reported unambiguous dose/concentrations; OPPT should modify/clarify this point for consistency in application.
9.4 Terminology for "Serious Flaws" and "Unacceptable" Criteria Should be Clarified OPPT has gone to extensive lengths to characterize study quality elements (e.g., serious flaws) that render a given study unacceptable for use. This is important to providing evidence-based assessments that reflect the best science. The presentation of such criteria are provided in separate tables - (1) tables of serious flaws and (2) data quality criteria [Score of 4]). Thus, such information overlaps and/or is duplicative. While the replicate tables are helpful, the terminology should be consistent. As presented in the current draft, it is slightly confusing as it suggests there are additional sets of criteria to consider (when in fact they are the same/similar criteria).

Problem Formulation Documents - Public Comments

1-BP SPECIFIC COMMENTS

#	Submitter	Attachments (#)	Category
1	Healey_CommentAugust72018	1	General
2	Healey_CommentAugust72018	1	Other, Policy
3	Healey_CommentAugust72018	1	Other, Policy

Document Section #
N/A
N/A
N/A

Comment
In Massachusetts, the Toxics Use Reduction Institute ("TURI"), created under TURA, Section 6, and the Massachusetts Office of Technical Assistance and Technology ("OTA"), its partner agency, work with Massachusetts businesses to reduce the use of toxic chemicals in the state. TURI and OTA are engaged in on-going work to help Massachusetts businesses and communities reduce their use of toxic solvents including trichloroethylene, perchloroethylene, methylene chloride, 1-bromopropane, and n-methylpyrrolidone, as well as helping businesses adopt safer alternatives to toxic flame retardants, among other efforts. This work to assist Massachusetts businesses and communities complements other regulatory activities within the Commonwealth to protect workers, communities and the environment from these and other toxic chemicals.
With the exception of HBCD and Pigment Violet 29, each of the Initial Ten TSCA Chemicals is listed as either a carcinogen and/or reproductive toxin under California's Safe Drinking Water and Toxic Enforcement Act of 1986 known as "Proposition 65."
New York: New York regulates the manufacture, sale, use and disposal of chemicals, including some at issue in the Problem Formulations, in a variety of ways. For example, New York has a de facto ban on the use of 1-bromopropane, also known as n-propyl bromide, in dry cleaning. New York will not issue an Air Facility Registration to any facility proposing to use that chemical as an alternative dry cleaning solvent as it is not an approved alternative solvent.

RAD POC	Docket #	Action Needed

4	Healey_CommentAugust72018	1	Other, Policy
5	Healey_CommentAugust72018	1	Other, Policy

N/A
N/A

Oregon: Oregon has adopted, and is considering, several state-specific statutes and regulations to manage the impacts of toxic and hazardous pollutants that encompass the majority of the Initial Ten TSCA Chemicals. These programs include: • Asbestos emissions, disposal, licensing and certification requirements. From 2011–2015, the CDC reports there were 245 new cases of mesothelioma in Oregon, resulting in 223 deaths. • Air toxics permits and benchmarks for industrial facilities. In addition, Oregon is currently in the process of developing new rules on industrial air emissions that would regulate emissions based on health risks to neighboring communities. The proposed rules will regulate emissions of hundreds of chemicals, including several of the Initial Ten TSCA Chemicals: asbestos, 1-bromopropane, carbon tetrachloride, 1,4 dioxane, tetrachloroethylene, and trichloroethylene. Oregon is relying on federal guidance and expertise to help define potential health risks for communities that are exposed to these emissions and to ensure that communities are protected from cumulative risks from other potential exposure pathways. • Toxics Use and Hazardous Waste Reduction planning requirements, which apply to large and small quantity generators of hazardous waste and Toxic Release Inventory reporters. • State cleanup and remedial actions for hazardous substances, and separate rules for dry cleaning facilities with perchloroethylene (tetrachloroethylene). In addition, legacy contamination from industrial sites is still a potential source of exposure to several of the Initial Ten TSCA Chemicals. The Oregon Health Authority's Environmental Health Assessment Program evaluates potential public health risks from contaminated sites across our state. In the last year alone, the program has been asked to evaluate public health risks from sites where environmental monitoring projects detected at least one of the Initial Ten TSCA Chemicals, including 1,4 dioxane, carbon tetrachloride, methylene chloride, tetrachloroethylene, and/or trichloroethylene. • Oregon adopted the Toxic Free Kids Act in 2015, requiring manufacturers of children's products to report the presence of specific chemicals of concern in products sold in Oregon. Several of the Initial Ten TSCA Chemicals are being reported in that program, including 1,4 dioxane, methylene chloride, tetrachloroethylene, and hexabromocyclododecane. Oregon relies on information from federal agencies to evaluate potential health risks of chemicals of concern for children, to identify new chemicals of concern to add to the reporting list, and to help address cumulative risks from these chemicals through other routes of exposure.
Distric of Columbia: The District of Columbia's Hazardous Waste Management Act includes provisions for toxic chemical source reporting and reduction. Businesses identified by the Standard Industrial Classification (SIC) as the largest generators or within the top 25% of all hazardous waste generators within the District, or that release a toxic chemical subject to regulation are required to file an annual Toxic Release Inventory (TRI) Form R for each TRI-listed chemical it manufactures, processes or otherwise uses in quantities above the threshold reporting quantity. In addition, reporting facilities must prepare and submit a toxic chemical source reduction plan which must be updated every four years. TRI-listed chemicals include the following toxic substances included in the Initial Ten TSCA Chemicals: trichloroethylene, 1-bromopropane and n-methylpyrrolidone.

6	ACOEMCommentAugust82018	1	General
7	ACOEMCommentAugust82018	1	Exposure
8	Anonymous2CommentAugust142018	1	General
9	Anonymous3CommentAugust132018	1	General

N/A
N/A
N/A
N/A

The American College of Occupational and Environmental Medicine (ACOEM) is pleased to respond to the EPA's request for comments about its planned chemical evaluation for 1-bromopropane. EPA is requesting any information from the public on 1-bromopropane both domestically and internationally. ACOEM represents more than 4,000 physicians and other health care professionals specializing in the field of occupational and environmental medicine (OEM). Founded in 1916, ACOEM is the nation's largest medical society dedicated to promoting the health of workers through preventive medicine, clinical care, research, and education. A dynamic group of physicians encompassing specialists in a variety of medical practices is united via the College to develop positions and policies on vital issues relevant to the practice of preventive medicine both within and outside of the workplace.
We recognize that the literature on the health effects of exposure to 1-bromopropane is extensive. Additionally, ACOEM recognizes that occupationally exposed workers represent a particular susceptible subpopulation, deserving of special scrutiny. At present OSHA has not set a permissible exposure limit for occupational exposures to 1-bromopropane, although ACGIH (and what other authority, NIOSH?) have recommended that such occupational exposures be rigorously controlled, with a recommended TLV of 0.1 ppm. NIOSH has proposed a Recommended Exposure Limit of 0.3 ppm. In 2009, Cal/OSHA set a permissible exposure of 5 ppm, for occupational exposures within California. The National Toxicology Program has listed 1-bromopropane as reasonably anticipated to be a human carcinogen. ACOEM urges EPA to consider both the cancer and non-cancer health effects resulting from exposure to 1-bromopropane, particularly in occupationally exposed populations where exposure is likely to be highest.
This is a product long known to have harmful effects and should be banned. We should move on to better and safer products not revisit them.
I resent the fact that the EPA has failed in the past year and a half to protect American taxpayers from dangerous chemicals. Please do not permit 1-Bromopropane to be used in the US. Thank you!

10	ICLCommentJuly182018	2	Human Health
11	ICLCommentJuly182018	2	Human Health

2.4.2.2
2.4.2.2

ICL would like the Agency to consider the outcome of the following study when evaluating the genotoxicity data of the substance. We would like to emphasis the rational and justification of doses selection. ICL has recently obtained the study to support n-Propyl Bromide (1-Bromopropane) REACH registration. The title of the study is identified below: In Vivo Mutation Assay of n-Propyl Bromide at the cII Locus in Big Blue® Transgenic B6C3F1 Mice Exposed via Whole-Body
A copy of the study's summary is attached with this comment. ICL submitted a copy of the full report to EPA for the consideration of the TSCA Work Plan Chemical Risk Assessment Review for 1-Bromopropane (n-Propyl Bromide). ICL would also like to emphasize that the doses of the OECD 488 study by ICL followed the doses used in the NTP study for the product, as can be seen in the following extract from the final report: "The test substance, n-propyl bromide, was administered via whole-body inhalation exposure for 6 hours per day for 28 consecutive days to 3 groups (Groups 2, 3 and 4) of female BigBlue® B6C3F1 mice. Target exposure concentrations were 62.5, 125 and 250 ppm for Groups 2, 3 and 4, respectively." "3.7.3 Justification for Selection of Exposure Route, Exposure Levels and Sex of Animals The dose route, target exposure concentrations and exposure regimen (6 hours per day for 7 days per week) for a 28-day period were selected by the Sponsor's Representative and are consistent with those recommended in OECD Test Guideline 488 (OECD, 2013). The National Toxicology Program (NTP) report on 1-bromopropane showed an increase in lung tumors with the highest incidence in female mice in a 2-year cancer study (NTP, 2013). The NTP study was conducted using the inhalation route at test concentrations of 62.5, 125 and 250 ppm. In order to replicate the tumorigenic dose levels and exposure conditions, the same approach was taken for this study with the modification of exposure using the OECD TG488-specified 7 day/week exposure, 28 days dosing regimen. The design is sufficient to permit genetic damage and fixation of the damage into detectable mutants."

12	ICLCommentJuly182018	2	Human Health
13	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure

2.4.2.2
2.2.2, 2.3.5

The experimental data shows clearly that treatment with n-Propyl Bromide did not cause statistically elevated mutant frequencies at the cII gene in liver and lungs of Big Blue® female mice. The positive control treatment with ENU produced statistically significant increases in mutant frequencies for both tissues tested, demonstrating the utility of the test system to detect and quantify induced mutants following exposure to a known direct acting mutagen. The study design and results obtained met protocol-specified assay acceptance criteria and were consistent with the study requirements of OECD TG 488 for transgenic rodent mutation assays, supporting the conclusion that n-Propyl Bromide is negative for the induction of cII mutants in liver and lungs of Big Blue® female mice under the conditions of testing. Therefore, it can be concluded that the carcinogenic pathway of this substance is not genotoxic, and that it depends on exposure threshold. If you have any questions or need additional information, please feel free to contact us.
A. The City's Substantive Concerns The Problem Formulations relate to ten different chemicals used across a spectrum of applications and industries, many of which (including, Methylene chloride, Perchloroethene, and Trichloroethene) are used frequently in the City in facilities that, because of our dense urban environment, are co-located in or adjacent to buildings where other people, including sensitive receptors, use the buildings for residential or commercial purposes. Others are currently used with less frequency, but off-gas into the air of buildings because they are present in soil vapor or groundwater (for instance, Carbon tetrachloride and 1-Bromopropane). For instance, dry cleaners are often in residential buildings where children may live or be cared for, or next to schools. Often, these chemicals are used in mixed-use zoning districts where residential and commercial uses are permitted to exist adjacent to or co-located with manufacturing uses. Because of these uses, the City is concerned about the limitations that EPA has set forth in the Problem Formulations that exclude from consideration certain exposure pathways. [Attachment A; comments dated 7/13/18]

14	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure, PESS
15	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure

2.2, 2.3.5
2.2, 2.3.5

The wide variety of chemicals to which construction workers are exposed is evident from a pilot study completed by CPWR - The Center for Construction Research and Training in January 2018. The pilot study asked 196 safety and health trainers from four different construction unions to identify common chemical hazards encountered in their trades. The trainers identified 63 different common chemical hazards in their trade, including some of the priority chemicals. The results were instructive, as they revealed not only the large numbers and wide range of chemicals which construction workers regularly encounter, but they showed that even these well-informed trainers did not necessarily know which specific chemicals are present in the products they use. For example, while almost two thirds of trainers listed adhesives as a common hazard, less than one fifth reported 1-bromopropane, methylene chloride, perchloroethylene, or trichloroethylene as a common hazard, even though these chemicals are known components of some adhesives.
Results from the survey related to the 10 priority chemicals are in Table 1, which is divided into two parts. The first part of the table lists chemicals specifically identified by the trainers. The second part lists products they identified, which may contain one or more priority chemicals including: • Adhesives may contain 1,4-dioxane, 1-BP, carbon tetrachloride, methylene chloride, NMP, PERC, or TCE; • Coil cleaner may contain 1,4-dioxane, 1-BP, carbon tetrachloride, methylene chloride, NMP, PERC, or TCE; • Degreaser may contain 1,4-dioxane, 1-BP, PERC, or TCE; • Flame retardant may contain HBCD; • Lubricants may contain 1,4-dioxane, methylene chloride, PERC, or TCE; • Paints and coatings may contain 1,4-dioxane, 1-BP, carbon tetrachloride, NMP, PERC, or pigment violet 29; and • Soldering flux may contain NMP. [Table 1: CPWR Pilot Survey Results of Construction Trainers – Common Chemical Hazards Frequency and Control Use, Priority Chemicals, p. 6 of EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU]

16	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure, Policy, RegNex

2.5

In addition to air and water, EPA has decided not to consider exposures arising from wastes, specifically stating that "EPA does not expect to include on-site releases to land from industrial non-hazardous and construction/demolition waste landfills". See e.g., Problem Formulation Document for 1-BP at 55, Problem Formulation Document for 1,4-dioxane at 45, Problem Formulation Document for TCE at 56, Problem Formulation Document for methylene chloride at 56, Problem Formulation Document for NMP at 51, Problem Formulation Document for PERC at 62. EPA justifies excluding this pathway from its risk assessment because wastes are primarily regulated under state programs, while also acknowledging that not all states require the same waste disposal protections. Yet, construction workers are routinely involved in handling, storage, and transporting waste materials that potentially contain the priority chemicals. All fourteen building trades unions participate in hazardous waste operations and emergency response (HAZWOPER) activities and Department of Energy site construction and remediation. Removal and disposal tasks can involve cutting, abrading, grinding, demolishing, digging, crushing, loading, and unloading resulting in exposure. It is only by first assessing whether these chemicals pose an unreasonable risk, and then by examining whether the state programs sufficiently address those risks that EPA can satisfy its statutory mandate to decide whether further regulation is required. See §6(a).

17	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure, PESS
18	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy
19			

2.2.2
N/A

EPA's decision not to assess products contaminated by the priority chemicals similarly eliminates a source of exposure for construction workers. Construction workers also are routinely called upon to use contaminated products, clean up contaminated environments, or remove structures built with contaminated products. Each of these tasks can generate chemicals and contaminated dusts, which is inhaled, absorbed through the skin and taken home on clothing. EPA cannot determine that these types of exposures would "present only de minimis exposure or otherwise insignificant risk" and should be excluded from evaluation without providing science-based evidence. See e.g., Problem Formulation Document for 1-BP at 21. Additionally, while contaminated products may not be an intended use, they are a "known or reasonably foreseeable use." §3(4). Worker exposures to contaminated products must be included in the scope for a comprehensive risk assessment of the priority chemicals to which construction workers, as a susceptible subpopulation, are reasonably expected to be exposed.

Even without IRIS assessments, the risks of many substances have been thoroughly reviewed and determined by the Agency and other authoritative bodies but these earlier findings will now be subject to revision as EPA reinterprets studies using its TSCA systematic review document. For example, 1-Bromopropane is classified by the National Toxicology Program as "reasonably anticipated" to cause cancer in humans. In 2016 the EPA Draft Risk Assessment recognized the relevance and reliability of this health endpoint when it derived an inhalation unit risk estimate based on lung tumors. So, it is particularly disturbing that the problem formulation for this chemical states that the "the weight-ofevidence analysis for the cancer endpoint is inconclusive" and it will be evaluated using the flawed TSCA systematic review (EPA 2018 Problem Formulation, p. 45). The concern raised by SCHF, NRDC, and others regarding the industry bias of the TSCA systematic review document makes it likely that a reanalysis will result in a false negative – that is, discounting evidence of cancer (see comments on TSCA systematic review by SCHF, NRDC, Docket EPA-HQ-OPPT-2018-0210 incorporated by reference).

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Problem Formulation Documents - Public Comments

1,4-DIOXANE SPECIFIC COMMENTS

#	Submitter	Attachments (#)	Category	Document Section #
1	APHA	1	Exposure	N/A
2	APHA	1	Exposure	N/A
3	APHA	1	Exposure	N/A

Comment
For example, the agency relies on information from "several racing authorities" to conclude that dioxane is no longer used as a fuel additive in car racing. Even though the racing authorities "could not provide credible information on...whether [dioxane] is currently used at all," the agency nonetheless determined that "fuels and fuel additives" are not a condition of use for the purposes of the 1,4-dioxane risk evaluation and will be excluded.
For example, even if domestic manufacture of 1,4-dioxane is included in the scope of the risk evaluation, inhalation of 1,4-dioxane in ambient air or ingestion of 1,4-dioxane in drinking water as a result of releases by domestic manufacturers will be excluded.
For example, the agency said it intends to exclude exposure to 1,4-dioxane in drinking water because drinking water contaminants may be regulated under the Safe Drinking Water Act. (Notably, the agency does not regulate 1,4-dioxane under the Safe Drinking Water Act, nor has it proposed to do so.) EPA acknowledges that "[t]he general population may ingest 1,4-dioxane via contaminated drinking water." EPA reports that 341 water systems have measured 1,4-dioxane at concentrations associated with an excess cancer risk greater than or equal to one in one million. This level of risk "has often been considered a "benchmark" above which EPA has concerns for exposure to the general population" — that is,the agency has considered this level of risk to be unreasonable. Because EPA is excluding drinking water exposure to 1,4-dioxane from the risk evaluation, however, this unreasonable risk will be ignored.

RAD POC	Docket #	Action Needed

4	BASF_CommentJuly62018	1	Exposure	N/A
5	BASF_CommentJuly62018	1	Exposure	N/A
6	Healey_CommentAugust72018	1	Other, Policy	N/A

BASF appreciates the opportunity to add information to Docket No.: EPA-HQ-OPPT-2016-0723 in response to the EPA document dated May 2018 "Problem Formulation of the Risk Evaluation for 1,4-Dioxane". BASF would like to make you aware that in April 2018 we informed our customers that BASF will cease the manufacturing 1,4-Dioxane (CAS 123-91-1) from our manufacturing location in Zachary LA USA by the end of 2018. We are currently in the process of qualifying our current customers to a source of imported material from BASF SE based in Ludwigshafen Germany. This decision to cease manufacturing of 1,4-Dioxane in the US is not a result of the EPA risk assessment activity - rather one based on economics and the declining sales and use of 1,4- Dioxane in North America.
We provide this information to EPA to assist you in prioritizing your assessment activities. Since BASF Corporation, as the sole producer of 1,4-Dioxane in the US, will no longer be manufacturing, you can remove any US manufacturing employee exposure risk assessment activities from your work plan. As mentioned, we may replace this with import of bulk material that will need to be repackaged to smaller quantities which may change your assessment activities. We felt this information may be of value for your continued assessment of 1,4- Dioxane and its potential exposures.
With the exception of HBCD and Pigment Violet 29, each of the Initial Ten TSCA Chemicals is listed as either a carcinogen and/or reproductive toxin under California's Safe Drinking Water and Toxic Enforcement Act of 1986 known as "Proposition 65."

7	Healey_CommentAugust72018	1	Other, Policy	N/A
8	Healey_CommentAugust72018	1	Other, Policy	N/A

The adverse impacts to California these substances cause are further demonstrated by the following: • From 2011–2015, the CDC reports there were 1,716 new cases of mesothelioma in California, resulting in 1,318 deaths. Asbestos exposure is the known cause of mesothelioma. • There have been at least two deaths in California caused by exposure to paint strippers containing methylene chloride since 2012. • There are 37 sites in California with TCE contamination that have been or are on the National Priorities List (NPL) under the Comprehensive Environment Response, Compensation and Liability Act (CERCLA), 29 with PCE contamination, 6 with asbestos contamination, 10 with 1,4-dioxane contamination, 36 with methylene chloride contamination, and 25 with carbon tetrachloride contamination. • In 2016, the most current Toxic Release Inventory (TRI) reporting year, a combined total of 2,124,369 pounds of 1,4-dioxane, asbestos, carbon tetrachloride, NMP, PCE and TCE was reported as having been disposed of or released in California.
To help remove 1,4-dioxane from drinking water on Long Island, New York has conditionally approved a new treatment technology.

9	Healey_CommentAugust72018	1	Other, Policy	N/A

Oregon: Oregon has adopted, and is considering, several state-specific statutes and regulations to manage the impacts of toxic and hazardous pollutants that encompass the majority of the Initial Ten TSCA Chemicals. These programs include:

- Asbestos emissions, disposal, licensing and certification requirements. From 2011–2015, the CDC reports there were 245 new cases of mesothelioma in Oregon, resulting in 223 deaths.
- Air toxics permits and benchmarks for industrial facilities. In addition, Oregon is currently in the process of developing new rules on industrial air emissions that would regulate emissions based on health risks to neighboring communities. The proposed rules will regulate emissions of hundreds of chemicals, including several of the Initial Ten TSCA Chemicals: asbestos, 1-bromopropane, carbon tetrachloride, 1,4 dioxane, tetrachloroethylene, and trichloroethylene. Oregon is relying on federal guidance and expertise to help define potential health risks for communities that are exposed to these emissions and to ensure that communities are protected from cumulative risks from other potential exposure pathways.
- Toxics Use and Hazardous Waste Reduction planning requirements, which apply to large and small quantity generators of hazardous waste and Toxic Release Inventory reporters.
- State cleanup and remedial actions for hazardous substances, and separate rules for dry cleaning facilities with perchloroethylene (tetrachloroethylene). In addition, legacy contamination from industrial sites is still a potential source of exposure to several of the Initial Ten TSCA Chemicals. The Oregon Health Authority's Environmental Health Assessment Program evaluates potential public health risks from contaminated sites across our state. In the last year alone, the program has been asked to evaluate public health risks from sites where environmental monitoring projects detected at least one of the Initial Ten TSCA Chemicals, including 1,4 dioxane, carbon tetrachloride, methylene chloride, tetrachloroethylene, and/or trichloroethylene.
- Oregon adopted the Toxic Free Kids Act in 2015, requiring manufacturers of children's products to report the presence of specific chemicals of concern in products sold in Oregon. Several of the Initial Ten TSCA Chemicals are being reported in that program, including 1,4 dioxane, methylene chloride, tetrachloroethylene, and hexabromocyclododecane. Oregon relies on information from federal agencies to evaluate potential health risks of chemicals of concern for children, to identify new chemicals of concern to add to the reporting list, and to help address cumulative risks from these chemicals through other routes of exposure.

10	UCSF_CommentJune252028	2	Exposure	2.2
11	UCSF_CommentJune252029	2	Exposure	2.2

Another example is 1,4-dioxane, which was historically used as a chemical stabilizer for chlorinated solvents. Many groundwater aquifers are contaminated with 1,4-dioxane, and the extent of legacy contamination of groundwater is likely underestimated. Also, 1,4-dioxane occurs in a wide variety of products including personal care products, detergents, waxes, and antifreeze, and 1,4-dioxane is a byproduct in manufacturing processes involving ethylene oxide, such as the production of polyethylene terephthalate (PET), polyester, and surfactants. The use and disposal of 1,4-dioxane has led to past environmental contamination which contributes to on-going exposures. The physical and chemical properties of 1,4-dioxane render it a persistent and highly mobile water contaminant: it is highly miscible in water. Exposures via drinking water are documented back to the 1980s and continue today. Results from EPA's Third Unregulated Contaminant Monitoring Rule (UCMR3) highlight that over 13% of 4,905 public drinking water systems serving >10,000 people had concentrations of 1,4-dioxane above the EPA Reference Concentration of 0.35 ppb 1,4-dioxane. Furthermore, the UCMR3 results do not capture exposures in communities served by small public drinking water systems serving <10,000 people. Approximately 27% of the US population is served by small public drinking water systems. Thus, it will be critical for EPA to consider the population's current exposure to 1,4-dioxane via sources like drinking water as part of their assessment for health risks.
When a chemical is present in products or media as a contaminant/ by-product, EPA needs to include and assess these exposures. We strongly recommend against ignoring or discounting these potential exposures routes. For example, EPA proposes to exclude from consideration conditions of use of 1,4-dioxane when it is present as contaminant in a wide variety of items, including household detergents, cosmetics/ toiletries, and foods. [p. 21 of Scope] This exclusion is not scientifically justified. Cosmetics and personal care products have the potential to contribute significantly to exposures, since people are applying them directly to their bodies, often multiple times per day, every day.

12	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure	2.2, 2.3.5

Results from the survey related to the 10 priority chemicals are in Table 1, which is divided into two parts. The first part of the table lists chemicals specifically identified by the trainers. The second part lists products they identified, which may contain one or more priority chemicals including:

- Adhesives may contain 1,4-dioxane, 1-BP, carbon tetrachloride, methylene chloride, NMP, PERC, or TCE;
- Coil cleaner may contain 1,4-dioxane, 1-BP, carbon tetrachloride, methylene chloride, NMP, PERC, or TCE;
- Degreaser may contain 1,4-dioxane, 1-BP, PERC, or TCE;
- Flame retardant may contain HBCD;
- Lubricants may contain 1,4-dioxane, methylene chloride, PERC, or TCE;
- Paints and coatings may contain 1,4-dioxane, 1-BP, carbon tetrachloride, NMP, PERC, or pigment violet 29; and
- Soldering flux may contain NMP.

[Table 1: CPWR Pilot Survey Results of Construction Trainers – Common Chemical Hazards Frequency and Control Use, Priority Chemicals, p. 6 of EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU]

13	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure, Policy, RegNex	2.5

In addition to air and water, EPA has decided not to consider exposures arising from wastes, specifically stating that "EPA does not expect to include on-site releases to land from industrial non-hazardous and construction/demolition waste landfills". See e.g., Problem Formulation Document for 1-BP at 55, Problem Formulation Document for 1,4-dioxane at 45, Problem Formulation Document for TCE at 56, Problem Formulation Document for methylene chloride at 56, Problem Formulation Document for NMP at 51, Problem Formulation Document for PERC at 62. EPA justifies excluding this pathway from its risk assessment because wastes are primarily regulated under state programs, while also acknowledging that not all states require the same waste disposal protections. Yet, construction workers are routinely involved in handling, storage, and transporting waste materials that potentially contain the priority chemicals. All fourteen building trades unions participate in hazardous waste operations and emergency response (HAZWOPER) activities and Department of Energy site construction and remediation. Removal and disposal tasks can involve cutting, abrading, grinding, demolishing, digging, crushing, loading, and unloading resulting in exposure. It is only by first assessing whether these chemicals pose an unreasonable risk, and then by examining whether the state programs sufficiently address those risks that EPA can satisfy its statutory mandate to decide whether further regulation is required. See §6(a).

14	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General	N/A
15	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Human Health	2.4.2
16	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A

• Six of the 10 chemicals – asbestos (and Libby amphibole asbestos), trichloroethylene (TCE), methylene chloride (MC), carbon tetrachloride (CTA), perchloroethylene (PERC) and 1,4-dioxane – have been assessed under the EPA Integrated Risk Information System (IRIS). The IRIS process is the Agency's authoritative mechanism for reviewing available studies and characterizing the health effects of chemicals. The problem formulations, however, indicate that EPA will revisit the interpretation of studies already evaluated in IRIS using its highly questionable TSCA "systematic review" method that has not been peer reviewed. This may lead to departures from IRIS determinations of the "best available science" and "weight of the evidence." Reopening IRIS findings would harm the public by prolonging uncertainty on issues that have been addressed and resolved through an authoritative and transparent process. In rare cases where significant new data (since the IRIS assessment) are available, the EPA TSCA program should rely on the IRIS program to review, assess, and if appropriate incorporate any new information using a systematic review method that is consistent with the state of the science. (Section X, pages 25-28)
1,4 Dioxane. For this chemical, there is little or no information on the potential for developmental toxicity or developmental neurotoxicity. This is especially problematic given that the chemical is a well-known neurotoxic agent. This critical data gap was identified by ATSDR in its 2012 Tox Profile.
X. EPA Should Not Revisit Definitive Findings in IRIS Assessments Unless There Are New Data That Inform EPA's Evaluation of the Weight of the Evidence Six of the 10 chemicals -- asbestos, TCE, MC, CTC, PERC and 1,4-dioxane -- have been assessed under the EPA Integrated Risk Information System (IRIS). The IRIS process is the Agency's authoritative mechanism for reviewing available studies, characterizing the health effects of chemicals and identifying concentrations below which these chemicals are not likely to cause adverse effects. IRIS assessments typically reflect years of work by EPA scientists, multiple rounds of public comment, inter and intraagency consultation, and extensive peer review, often by the Agency's independent Science Advisory Board (SAB) or the National Academy of Sciences (NAS). The IRIS program recently received a favorable review from the NAS.

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Problem Formulation Documents - Public Comments

PERC SPECIFIC COMMENTS

#	Submitter	Attachments (#)	Category
1	Healey_CommentAugust72018	1	General
2	Healey_CommentAugust72018	1	Other, Policy
3	Healey_CommentAugust72018	1	Other, Policy

Document Section #
N/A
N/A
N/A

Comment
In Massachusetts, the Toxics Use Reduction Institute ("TURI"), created under TURA, Section 6, and the Massachusetts Office of Technical Assistance and Technology ("OTA"), its partner agency, work with Massachusetts businesses to reduce the use of toxic chemicals in the state. TURI and OTA are engaged in on-going work to help Massachusetts businesses and communities reduce their use of toxic solvents including trichloroethylene, perchloroethylene, methylene chloride, 1-bromopropane, and n-methylpyrrolidone, as well as helping businesses adopt safer alternatives to toxic flame retardants, among other efforts. This work to assist Massachusetts businesses and communities complements other regulatory activities within the Commonwealth to protect workers, communities and the environment from these and other toxic chemicals.
California: Because of the significant harm to human health and the environment that the Initial Ten TSCA Chemicals pose, California has implemented regulatory measures including, but not limited to: prohibiting the sale, supply, and manufacturing for use of specified consumer product categories that contain any of the following compounds: TCE, PCE, or methylene chloride; regulating exposure to asbestos in construction work, general industry, shipyards and prohibiting sale of brake pads with asbestiform fibers above .1% weight.
With the exception of HBCD and Pigment Violet 29, each of the Initial Ten TSCA Chemicals is listed as either a carcinogen and/or reproductive toxin under California's Safe Drinking Water and Toxic Enforcement Act of 1986 known as "Proposition 65."

RAD POC	Docket #	Action Needed

4	Healey_CommentAugust72018	1	Other, Policy
5	Healey_CommentAugust72018	1	Other, Policy
6	Healey_CommentAugust72018	1	Other, Policy

N/A
N/A
N/A

The adverse impacts to California these substances cause are further demonstrated by the following: • From 2011–2015, the CDC reports there were 1,716 new cases of mesothelioma in California, resulting in 1,318 deaths. Asbestos exposure is the known cause of mesothelioma. • There have been at least two deaths in California caused by exposure to paint strippers containing methylene chloride since 2012. • There are 37 sites in California with TCE contamination that have been or are on the National Priorities List (NPL) under the Comprehensive Environment Response, Compensation and Liability Act (CERCLA), 29 with PCE contamination, 6 with asbestos contamination, 10 with 1,4-dioxane contamination, 36 with methylene chloride contamination, and 25 with carbon tetrachloride contamination. • In 2016, the most current Toxic Release Inventory (TRI) reporting year, a combined total of 2,124,369 pounds of 1,4-dioxane, asbestos, carbon tetrachloride, NMP, PCE and TCE was reported as having been disposed of or released in California.
Maine: Under the Maine Priority Toxic Chemical Use Reduction law, 38 Maine Revised Statutes ("M.R.S.") §§ 2331-2330, and corresponding rule, 06-096 Code of Maine Rules ("CMR") ch. 82, commercial and industrial facilities using more than 1,000 pounds/year of a priority toxic chemical listed in Maine's rule, 06-096 CMR ch. 81, must report their usage of the chemical and must develop a pollution prevention plan, which must be updated every two years. Maine has identified five chemicals as priority toxic chemicals under this law, two of which are on the list of Initial Ten TSCA Chemicals—perchloroethylene and trichloroethylene.
Maine regulates several of the chemicals on the list of Initial Ten TSCA Chemicals as hazardous matter and hazardous substances. In addition, Maine regulates control technology for dry cleaners using perchloroethylene.

7	Healey_CommentAugust72018	1	Other, Policy
8	Healey_CommentAugust72018	1	Other, Policy

N/A
N/A

More broadly, the Department regulates the disposal of hazardous waste, including substances included in EPA's Initial Ten TSCA Chemicals. Maryland Department of the Environment regulations generally prohibit the sale, supply, offer for sale, or manufacture for use in the state of adhesives, cleaners, and other products containing methylene chloride, perchloroethylene, or trichloroethylene. Additionally, the Maryland Secretary of Health may declare a substance to be "hazardous material" and establish labeling requirements or, where appropriate, ban the substance. The Secretary has exercised this authority by incorporating by reference Parts 1500 and 1505 of Title 16 of the Code of Federal Regulations (implementing the Federal Hazardous Substances Act). The Secretary is authorized to inspect facilities where hazardous material may be manufactured, processed, packaged, or stored, as well as vehicles used to transport or hold such material.
New York has spent millions of dollars cleaning up tetrachloroethylene (perc) and trichloroethylene at hazardous waste sites.

9	Healey_CommentAugust72018	1	Other, Policy
10	Healey_CommentAugust72018	1	Other, Policy

N/A
N/A

Oregon: Oregon has adopted, and is considering, several state-specific statutes and regulations to manage the impacts of toxic and hazardous pollutants that encompass the majority of the Initial Ten TSCA Chemicals. These programs include: • Asbestos emissions, disposal, licensing and certification requirements. From 2011–2015, the CDC reports there were 245 new cases of mesothelioma in Oregon, resulting in 223 deaths. • Air toxics permits and benchmarks for industrial facilities. In addition, Oregon is currently in the process of developing new rules on industrial air emissions that would regulate emissions based on health risks to neighboring communities. The proposed rules will regulate emissions of hundreds of chemicals, including several of the Initial Ten TSCA Chemicals: asbestos, 1-bromopropane, carbon tetrachloride, 1,4 dioxane, tetrachloroethylene, and trichloroethylene. Oregon is relying on federal guidance and expertise to help define potential health risks for communities that are exposed to these emissions and to ensure that communities are protected from cumulative risks from other potential exposure pathways. • Toxics Use and Hazardous Waste Reduction planning requirements, which apply to large and small quantity generators of hazardous waste and Toxic Release Inventory reporters. • State cleanup and remedial actions for hazardous substances, and separate rules for dry cleaning facilities with perchloroethylene (tetrachloroethylene). In addition, legacy contamination from industrial sites is still a potential source of exposure to several of the Initial Ten TSCA Chemicals. The Oregon Health Authority's Environmental Health Assessment Program evaluates potential public health risks from contaminated sites across our state. In the last year alone, the program has been asked to evaluate public health risks from sites where environmental monitoring projects detected at least one of the Initial Ten TSCA Chemicals, including 1,4 dioxane, carbon tetrachloride, methylene chloride, tetrachloroethylene, and/or trichloroethylene. • Oregon adopted the Toxic Free Kids Act in 2015, requiring manufacturers of children's products to report the presence of specific chemicals of concern in products sold in Oregon. Several of the Initial Ten TSCA Chemicals are being reported in that program, including 1,4 dioxane, methylene chloride, tetrachloroethylene, and hexabromocyclododecane. Oregon relies on information from federal agencies to evaluate potential health risks of chemicals of concern for children, to identify new chemicals of concern to add to the reporting list, and to help address cumulative risks from these chemicals through other routes of exposure.
In addition, under Washington's Children's Safe Products Act, manufacturers whose products contain certain chemicals, like N-Methylpyrrolidone, methylene chloride, tetrachloroethylene, and HBCD, must annually report to Ecology.

11	Healey_CommentAugust72018	1	RegNex, Human Health, Eco Health

2.2, 2.5.3

EPA claims in the Problem Formulation for perchloroethylene that it is not excluding any conditions of use for the chemical,[p. 22] while ignoring in the risk evaluation significant pathways for exposure to that chemical, finding that the chemical is adequately regulated under other identified regulatory programs under other statutes. [p. 59] While the protections under other regulatory schemes may reduce exposure potential, it is EPA's charge under TSCA to eliminate unreasonable risk to human health and the environment posed by the chemical, a mandate that only can be satisfied if EPA includes in its risk evaluations all known exposure pathways assessed cumulatively. Without a sound evaluation of those exposure pathways, whether potentially addressed by other regulatory schemes or not, EPA cannot fulfill its mandate to evaluate and eliminate unreasonable risks posed by these chemicals.

Perchloroethylene, known as perc, is a dry cleaning solvent and is also used as a metal degreaser, a chemical intermediate and an ingredient in consumer products, such as automotive aerosol parts cleaners and degreasers. Perc has been reported to be the chemical most widely found in groundwater contamination at Superfund sites. Acute exposures to perchloroethylene have been associated with dizziness, confusion, headache, nausea, and irritation of the eyes and mucous tissue, while exposure to extremely high levels of perc may lead to unconsciousness and, in extreme cases, death from respiratory depression. Long term exposure to perc may cause liver, kidney or central nervous system damage, and perc has been characterized by the International Agency on Research on Cancer (IARC) as "probably carcinogenic to humans."

12	Healey_CommentAugust72018	1	RegNex, Exposure
13	Healey_CommentAugust72018	1	Exposure/RegNex/Policy

2.5.3.2
2.5.3.2

In the perchloroethylene Problem Formulation, Section 2.5.3.2, EPA carves out recognized exposure pathways from its analysis: Pathways That EPA Does Not Expect to Include in the Risk Evaluation Exposures to receptors may occur from industrial and/or commercial uses, industrial releases to air, water or land; and other conditions of use. As described in [this section], pathways under other environmental statutes, administered by EPA, which adequately assess and effectively manage exposures and for which long-standing regulatory and analytical processes already exist will not be included in the risk evaluation." [p. 59] The Problem Formulation then identifies the statutory schemes under which perchloroethylene is regulated: (i) the Clean Air Act (regulates perc as a hazardous air pollutant and prescribes technology-based standards and other limitations as required for stationary source emissions of perchloroethylene); (ii) the Safe Drinking Water Act (sets Maximum Contaminant Levels for perc in drinking water); (iii) the federal Clean Water Act (perchloroethylene is a "priority pollutant" requiring the adoption of numeric criteria and discharge permit limits to protect surface water quality and perchloroethylene has been identified in biosolids reviews that EPA says it plans to address in the future); and (iv) the Resource Conservation and Recovery Act (RCRA) (perchloroethylene is a listed hazardous waste, the treatment, storage, and disposal of which is regulated under the act).
Even if EPA's actions under its separate regulatory programs for perchloroethylene described above serve to meet each statute's requirements for protections under that statute, relying on each of those individual mandates for addressing the chemical as a pollutant (mandates designed to reduce impacts and exposures but not eliminate them), provides no assurance that TSCA's mandate for eliminating unreasonable risks will be met because the potential cumulative effect of exposures to the chemical across environmental media must be considered in its evaluations.

14	UCSF_CommentJune252036	2	PESS
15	ACOEMCommentAugust82018	1	Exposure, RegNex, Human health
16	ACOEMCommentAugust82018	1	Exposure, Human Health
17	ACOEMCommentAugust82018	1	Fate

2.3.5
2.3.5
N/A
2.3., 2.6.1

For example, the prenatal lifestage is the most sensitive to developmental and reproductive toxicants, and women of child-bearing age should be considered as a susceptible sub-population for any chemicals with such hazards. Women of reproductive age are not specifically identified as a potential susceptible sub-population for pigment violet 29, TCE, NMP, PERC, or HBCD, even though EPA will consider reproductive and developmental toxicity hazards for these chemicals.
We recognize that the literature on the health effects of exposure to perchloroethylene (PCE) is extensive. Additionally, ACOEM recognizes that occupationally exposed workers represent a particularly susceptible subpopulation, deserving of special scrutiny. We further recognize that OSHA's current rule for exposure to PCE is likely not protective for neurological effects in exposed adults and is almost surely not protective for cancer and reproductive health effects.
The National Toxicology Program classifies PCE as "reasonably anticipated to be a human carcinogen." OSHA's current permissible exposure limit (PEL) for PCE (100 ppm for Federal OSHA, or 678 mg/cu m, as an 8-hour time-weighted average) would theoretically permit a worker to be exposed to as much as 4,750 mg of trichloroethylene per day, assuming a breathing rate of 10 cu meters per 8-hour shift and an absorption factor of about 70%. Exposures in this range over a lifetime would impose an incremental cancer risk for exposed workers markedly exceeding one chance in a hundred, taking account of the current cancer potency estimates for PCE. By contrast, ACOEM applauds EPA's previous calculation of a Reference Concentration (RfC) for PCE of 0.04 milligrams per cubic meter based on neurotoxicity in occupationally-exposed adults. We urge EPA to consider all sources of exposure to PCE in potentially exposed workers to assure that cumulative exposures from occupational uses, from ambient air, and/or from drinking water do not exceed an acceptable level.
In addition, ACOEM is concerned about the fate of PCE released into the environment, whether in the form of surface-run off, release from storage tanks, or other unintended releases. The extent of persistent groundwater contamination with PCE has been documented in many parts of the nation.

18	ACOEMCommentAugust82018	1	Human Health, PESS, Exposure
19	ACOEMCommentAugust82018	1	Fate
20	AnonymousCommentJuly242018	1	General, Exposure
21	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General, Editorial

2.3.5, 2.6.1
2.3., 2.6.1
2.6.1
N/A

Accordingly, ACOEM urges EPA to consider both the cancer and non-cancer health effects resulting from exposure to PCE, particularly in occupationally exposed populations for whom exposure is likely to be highest.
Furthermore, given the troubling worldwide record of environmental PCE contamination, particularly involving groundwater, ACOEM encourages EPA to include in its chemical evaluation the environmental fate and environmental impacts of PCE use, both from intended uses as well as from uses that may be unintended but are reasonably foreseeable.
Perchloroethylene is essential for cleaning mission-critical, high-value military flight hardware. The process is non-emissive (under one tenth of a pound lost to the air per year), with negligible worker exposure. Details were submitted to this docket as comment EPA-HQ-OPPT-2016-0732-0014 and are reported again to be responsive to the current EPA request for comments.
For example, Trichloroethylene (TCE) and Tetrachloroethylene (PERC) are among the most well-studied chemicals and are among those pollutants most prevalent in groundwater in the U.S. and elsewhere. It appears that the only difference between the scoping document and the Problem Formulation documents for these chemicals is that they have “refined” the conditions of use and exposure pathways, eliminating certain conditions of use and exposure pathways from consideration. It is unclear why these changes warranted a whole new document that impedes transparency, as it is difficult for the public to compare the Problem Formulations to the 2017 scope in order to understand the differences. It would be more helpful and easier for the public to understand any differences if EPA simply called the Problem Formulations amended scoping documents, rather than giving them new names and formats, insofar as scoping is an accepted mechanism to formulate problems for consideration in analysis.

22	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure
23	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure

2.2.2, 2.3.5
2.2.2, 2.3.5

TSCA also does not adequately address legacy uses of PERC, methylene chloride, carbon tetrachloride, and TCE, as well as bystander exposure to PERC.17 These chemicals are possible or probable human carcinogens and toxic to various organs including the kidney and liver. They are very frequently found in groundwater and soil vapor throughout the City. This "legacy" directly impacts many New Yorkers due to widespread historic (and often current) use and the dense urban environment. These chemicals enter buildings through the soil vapor and frequently cause residents to breathe concentrations that are well above health-based guidance values. However, the extent of this problem is poorly studied and not adequately addressed byany federal acts. Because whole buildings or neighborhoods are sometimes affected, attempting to remediate these chemicals after they have entered into groundwater and soils is expensive and time consuming, and occurs only after building occupants, including children, are exposed to them. In order to prevent human health consequences, and an extraordinary waste of resources, TSCA must regulate them before they are legacy pollution.
By disregarding the risks of legacy uses of all 10 chemicals, most importantly asbestos, PERC, methylene chloride, carbon tetrachloride, and TCE, EPA is excluding from its consideration the means by which many Americans may be exposed to these hazardoussubstances, and undercounting the net risks of exposure for all Americans.

24	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure

2.2.2, 2.3.5

A. The City's Substantive Concerns The Problem Formulations relate to ten different chemicals used across a spectrum of applications and industries, many of which (including, Methylene chloride, Perchloroethene, and Trichloroethene) are used frequently in the City in facilities that, because of our dense urban environment, are co-located in or adjacent to buildings where other people, including sensitive receptors, use the buildings for residential or commercial purposes. Others are currently used with less frequency, but off-gas into the air of buildings because they are present in soil vapor or groundwater (for instance, Carbon tetrachloride and 1-Bromopropane). For instance, dry cleaners are often in residential buildings where children may live or be cared for, or next to schools. Often, these chemicals are used in mixed-use zoning districts where residential and commercial uses are permitted to exist adjacent to or co-located with manufacturing uses. Because of these uses, the City is concerned about the limitations that EPA has set forth in the Problem Formulations that exclude from consideration certain exposure pathways. [Attachment A; comments dated 7/13/18]

25	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure

2.2.2, 2.3.5

First, the City has significant concerns about EPA's decision to remove from the risk evaluation certain activities and exposure pathways, including "activities that EPA concluded do not constitute conditions of use." [p. 21 of PF for PERC] This limitation deviates from the scope set forth in the June 2017 Scopes of Risk Evaluation, [Scope for PERC] which stated that EPA intended to "assess each use subcategory by identifying all potential sources of release and human exposure associated with that subcategory." [pp. 20-21 of Scope for PERC] By excluding activities and uses that are designated on a case by case basis as not constituting conditions of use,4 EPA will likely fail to consider potential exposures caused during manufacture and use of the product, such as accidental spills, or exposures that occur when the chemical is used properly when the facility is co-located with or adjacent to residential, educational, recreational, or commercial activities. For example, using trichloroethene (TCE) as a spot remover in a co-located dry cleaning facility on the ground floor may result in a resident on the floor above the facility being exposed to the TCE. [Attachment A; comments dated 7/13/18]

Footnote:

4 "Conditions of use" are defined by the Administrator and he or she has the authority to exclude conditions on case-by-case basis.

26	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure, RegNex

2.2.2, 2.3.5

Second, the City objects to EPA's exclusion of "exposure pathways [covered] under regulatory programs of other environmental statutes, administered by EPA, which adequately assess and effectively manage exposures and for which long-standing regulatory and analytical processes already exist, i.e., the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA) and the Resource Conservation and Recovery Act (RCRA)." [p. 54 of PF for PERC] While other governing statutes often address the same chemicals as TSCA regulations, they are often (if not exclusively) most effective in regulating contaminants after they are already in soil, water and air, or are focused on controlling discharges at a pipe or stack. These statutes often cannot prevent contaminants from entering the water, air, or soil in the first place, and are not intended to, and do not, ensure that chemical products are used safely and effectively. By failing to consider exposure pathways that result from spills or potential consequences of proper use that cause a chemical to enter the water, air, or soil, EPA will fail to properly account for exposures to the public, including New Yorkers, that result from TSCA-regulated activities. [Attachment A; comments dated 7/13/18]

27	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure
28	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General

2.2.2, 2.3.5
N/A

New York City has significant soil vapor exposure resulting from extensive use of Carbon tetrachloride, Methylene chloride, Perchloroethene, and Trichloroethene6 within our borders. This contamination results in health consequences not only for workers in the source facility, but also for adjacent or co-located workers, residents, and children. By curtailing TSCA, there will be further opportunities for these chemicals to enter the soil, air, groundwater, and buildings, exposing nearby New Yorkers and requiring unnecessary remediation in the future. [Attachment A; comments dated 7/13/18] Footnote: 6 Note, while 1-Bromopropane is not often found in City soil vapor. However, if 1-Bromopropane becomes more widely used (e.g., as a replacement solvent for PCE in dry cleaning) then it would likely be more abundant in the soil vapor. The City is hopeful that TSCA risk evaluators will consider the full implications of 1-Bromopropane and its potential for being a future contaminant. Additionally, if chlorinated compounds are replaced with brominated solvents, then other common workplace exposures to brominated solvents will likely increase in the future because the workplace practices are unlikely to change. The City recognizes that in the 1-Bromopropane Problem Formulation, EPA discusses inhalation of the chemical by people occupying businesses co-located with dry cleaners, and states that EPA will consider various issues relating to the chemical's waste, disposal, and use that may impact other non-occupational bystanders. However the Problem Formulation does not specifically discuss the inhalation of 1-Bromopropane in co-located homes.
Additionally, at the time of these comments, although some of the other docket numbers for the specifically referenced ten chemicals contained links to record documents, some did not, creating confusion. For example, Docket number EPA-HQ-OPPT-2016-732-0080, for PCE, shows the Problem Formulation document, but indicates that the comment period has closed. However, the Problem Formulation document is dated May 2018 and was posted in June 2018. [Attachment A; comments dated 7/13/18]

29	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure, PESS
30	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure

2.2, 2.3.5
2.2, 2.3.5

The wide variety of chemicals to which construction workers are exposed is evident from a pilot study completed by CPWR - The Center for Construction Research and Training in January 2018. The pilot study asked 196 safety and health trainers from four different construction unions to identify common chemical hazards encountered in their trades. The trainers identified 63 different common chemical hazards in their trade, including some of the priority chemicals. The results were instructive, as they revealed not only the large numbers and wide range of chemicals which construction workers regularly encounter, but they showed that even these well-informed trainers did not necessarily know which specific chemicals are present in the products they use. For example, while almost two thirds of trainers listed adhesives as a common hazard, less than one fifth reported 1-bromopropane, methylene chloride, perchloroethylene, or trichloroethylene as a common hazard, even though these chemicals are known components of some adhesives.
Results from the survey related to the 10 priority chemicals are in Table 1, which is divided into two parts. The first part of the table lists chemicals specifically identified by the trainers. The second part lists products they identified, which may contain one or more priority chemicals including: • Adhesives may contain 1,4-dioxane, 1-BP, carbon tetrachloride, methylene chloride, NMP, PERC, or TCE; • Coil cleaner may contain 1,4-dioxane, 1-BP, carbon tetrachloride, methylene chloride, NMP, PERC, or TCE; • Degreaser may contain 1,4-dioxane, 1-BP, PERC, or TCE; • Flame retardant may contain HBCD; • Lubricants may contain 1,4-dioxane, methylene chloride, PERC, or TCE; • Paints and coatings may contain 1,4-dioxane, 1-BP, carbon tetrachloride, NMP, PERC, or pigment violet 29; and • Soldering flux may contain NMP. [Table 1: CPWR Pilot Survey Results of Construction Trainers – Common Chemical Hazards Frequency and Control Use, Priority Chemicals, p. 6 of EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU]

31	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure, Policy, RegNex

2.5

In addition to air and water, EPA has decided not to consider exposures arising from wastes, specifically stating that "EPA does not expect to include on-site releases to land from industrial non-hazardous and construction/demolition waste landfills". See e.g., Problem Formulation Document for 1-BP at 55, Problem Formulation Document for 1,4-dioxane at 45, Problem Formulation Document for TCE at 56, Problem Formulation Document for methylene chloride at 56, Problem Formulation Document for NMP at 51, Problem Formulation Document for PERC at 62. EPA justifies excluding this pathway from its risk assessment because wastes are primarily regulated under state programs, while also acknowledging that not all states require the same waste disposal protections. Yet, construction workers are routinely involved in handling, storage, and transporting waste materials that potentially contain the priority chemicals. All fourteen building trades unions participate in hazardous waste operations and emergency response (HAZWOPER) activities and Department of Energy site construction and remediation. Removal and disposal tasks can involve cutting, abrading, grinding, demolishing, digging, crushing, loading, and unloading resulting in exposure. It is only by first assessing whether these chemicals pose an unreasonable risk, and then by examining whether the state programs sufficiently address those risks that EPA can satisfy its statutory mandate to decide whether further regulation is required. See §6(a).

32	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General
33	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure

N/A
2.6

• Six of the 10 chemicals – asbestos (and Libby amphibole asbestos), trichloroethylene (TCE), methylene chloride (MC), carbon tetrachloride (CTA), perchloroethylene (PERC) and 1,4-dioxane – have been assessed under the EPA Integrated Risk Information System (IRIS). The IRIS process is the Agency's authoritative mechanism for reviewing available studies and characterizing the health effects of chemicals. The problem formulations, however, indicate that EPA will revisit the interpretation of studies already evaluated in IRIS using its highly questionable TSCA "systematic review" method that has not been peer reviewed. This may lead to departures from IRIS determinations of the "best available science" and "weight of the evidence." Reopening IRIS findings would harm the public by prolonging uncertainty on issues that have been addressed and resolved through an authoritative and transparent process. In rare cases where significant new data (since the IRIS assessment) are available, the EPA TSCA program should rely on the IRIS program to review, assess, and if appropriate incorporate any new information using a systematic review method that is consistent with the state of the science. (Section X, pages 25-28)
III. There is No Legal or Technical Justification for Excluding General Population Exposure from EPA's Risk Evaluations Several of the problem formulations indicate that EPA will not evaluate the risks of general population exposure. As stated in the PERC problem formulation: EPA does not plan to consider and analyze general population exposures in the risk evaluation for PERC. EPA has determined that the existing regulatory programs and associated analytical processes have addressed or are in the process of addressing potential risks of TCE that may be present in various media pathways (e.g., air, water, land) for the general population. For these cases, EPA believes that the TSCA risk evaluation should focus not on those exposure pathways, but rather on exposure pathways associated with TSCA uses that are not subject to those regulatory processes.

34	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Human Health
35	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy

2.4.2
N/A

PERC. This chemical is considered by EPA to be both neurotoxic and a developmental toxicant, yet it has never been tested for developmental neurotoxicity. This is a major data gap, given that developmental neurotoxic effects such as learning impairments and behavioral problems are often overlooked in routine tests such as the ones EPA considered, which focus on crude frank toxicity such as reduced body or organ weights, stillbirths and deaths (see Perc problem formulation, p. 52). Lead, mercury, and other developmental neurotoxic chemicals have all been shown to have virtually no safe level when exposures occur prenatally during critical windows of neurodevelopment. For this reason, the EPA pesticide office began requiring pesticide registrants to submit developmental neurotoxicity testing – which includes subtle but important endpoints like motor activity, learning and memory, and auditory startle response – for the organophosphates and other pesticides known to be neurotoxic. In an EPA fact sheet issued last month, EPA emphasizes why specific developmental neurotoxicity tests are important: • The developing nervous system can be particularly sensitive to exposure to environmental chemicals. • Less than 1% of chemicals in the environment have been fully evaluated for their potential to be developmental neurotoxicants, or their impact on the developing nervous system. • Due to a lack of data, it is not possible to understand the extent or potential contribution of environmental chemicals in neurodevelopmental disease, nor predict the potential developmental neurotoxicity risk for individual chemicals. The failure to address the risks of developmental neurotoxicity posed by PERC represents a serious data gap in EPA's assessment, particular for the low-dose risks.
X. EPA Should Not Revisit Definitive Findings in IRIS Assessments Unless There Are New Data That Inform EPA's Evaluation of the Weight of the Evidence Six of the 10 chemicals -- asbestos, TCE, MC, CTC, PERC and 1,4-dioxane -- have been assessed under the EPA Integrated Risk Information System (IRIS). The IRIS process is the Agency's authoritative mechanism for reviewing available studies, characterizing the health effects of chemicals and identifying concentrations below which these chemicals are not likely to cause adverse effects. IRIS assessments typically reflect years of work by EPA scientists, multiple rounds of public comment, inter and intraagency consultation, and extensive peer review, often by the Agency's independent Science Advisory Board (SAB) or the National Academy of Sciences (NAS). The IRIS program recently received a favorable review from the NAS.

36	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Exposure

2.3

Second, a number of the OSHA standards that apply to chemicals subject to the first 10 risk evaluations were developed many years ago and do not reflect current data and scientific understanding of the health effects of the regulated chemicals.81 Thus, the levels of exposure allowed by these standards may be unsafe when evaluated using the best available science.

Footnote:

81 OSHA has two types of standards. Under section 6(a) of the OSH Act, OSHA adopted hundreds of PELs in 1971 that were, at that time, considered national consensus standards. They have not been updated since and are based on science from the 1960s or earlier. Since 1971, OSHA has regulated only about 40 chemicals under section 6(b). These more comprehensive standards are based on thorough evaluation of health effects and a determination that risks are significant. OSHA has 6(b) standards regulating only asbestos and MC. It has PELs (adopted under 6(a)) for PERC and TCE but not for the other 10 chemicals. In the case of both asbestos and MC, OSHA's published Federal Register preambles found that even at the revised PEL, employees continued to be exposed to significant risks i.e., risks above 1/1000 – OSHA's definition of significant risk.

Problem Formulation Documents - Public Comments

PV29 SPECIFIC COMMENTS

#	Submitter	Attachments (#)	Category	Document Section #
1	UCSF_CommentJune252036	2	PESS	2.3.5
2	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure	2.2, 2.3.5

Comment	RAD POC	Docket #	Action Needed
For example, the prenatal lifestage is the most sensitive to developmental and reproductive toxicants, and women of child-bearing age should be considered as a susceptible sub-population for any chemicals with such hazards. Women of reproductive age are not specifically identified as a potential susceptible sub-population for pigment violet 29, TCE, NMP, PERC, or HBCD, even though EPA will consider reproductive and developmental toxicity hazards for these chemicals.			
Results from the survey related to the 10 priority chemicals are in Table 1, which is divided into two parts. The first part of the table lists chemicals specifically identified by the trainers. The second part lists products they identified, which may contain one or more priority chemicals including: • Adhesives may contain 1,4-dioxane, 1-BP, carbon tetrachloride, methylene chloride, NMP, PERC, or TCE; • Coil cleaner may contain 1,4-dioxane, 1-BP, carbon tetrachloride, methylene chloride, NMP, PERC, or TCE; • Degreaser may contain 1,4-dioxane, 1-BP, PERC, or TCE; • Flame retardant may contain HBCD; • Lubricants may contain 1,4-dioxane, methylene chloride, PERC, or TCE; • Paints and coatings may contain 1,4-dioxane, 1-BP, carbon tetrachloride, NMP, PERC, or pigment violet 29; and • Soldering flux may contain NMP. [Table 1: CPWR Pilot Survey Results of Construction Trainers – Common Chemical Hazards Frequency and Control Use, Priority Chemicals, p. 6 of EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU]			

3	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A
4	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Human Health	2.4.2
5	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Human Health	N/A
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It is therefore disappointing that the problem formulations, like the earlier scoping documents, make minimal efforts to identify significant data gaps for the 10 chemicals, to set in motion development of additional information, and to address how these data gaps will impact the conclusions reached in the risk evaluations. Indeed, EPA seems ready to find that substances do not present an unreasonable risk of injury even where available data are lacking entirely or are insufficient under Agency guidelines to determine that a substance lacks adverse effects.37 Footnote: 37 The EPA responses to comments on the scoping documents indicate that: "when OPPT does find existing data are not adequate, OPPT will use all available authorities to fill data gaps necessary to conduct fit-for-purpose assessments." This is not, however, the approach reflected in the problem formulations.			
Thus, EPA could not reach scientifically defensible conclusions that pigment violet 29 lacks the potential to cause carcinogenicity, reproductive and developmental toxicity, developmental neurotoxicity, neurotoxicity, repeated dose toxicity or endocrine effects.			
Pigment violet 29 is not the only one of the 10 chemicals with significant data gaps. 1,4-dioxane, MC, PERC and TCE also lack data for important end-points:			

Problem Formulation Documents - Public Comments

HBCD SPECIFIC COMMENTS

#	Submitter	Attachments (#)	Category	Document Section #
1	APHA	1	Exposure	N/A
2	APHA	1	Exposure	N/A
3	NTTC	1	PESS	N/A
4	NTTC	1	PESS	N/A

Comment
For example, EPA has concluded that "domestic manufacture of HBCD has ceased" based primarily on assurances provided by two recent manufacturers of the flame retardant. The agency does not indicate how it verified these assurances or how it will ensure that the purported cessation will continue in the future.
The agency has excluded domestic manufacture of expanded polystyrene (EPS) resin and extruded polystyrene (XPS) masterbatch from the HBCD evaluation based on reports by "all major North American manufacturers...of EPS resin" and comments by "major producers" of XPS masterbatch (emphasis added), respectively. These reports cover only manufacturers or producers that the agency considers "major." They cannot represent the activities of any other manufacturers of EPS resin or XPS masterbatch, including any future manufacturers.
A risk assessment based on the HBCD Problem Formulation will not be protective of tribal, rural, or urban subsistence populations as it fails to identify exposed subpopulations. Consequently, unless the Problem Formulation is changed to explicitly address these populations, the EPA Administrator will fail to carry out requirements as mandated by Congress in TSCA, as amended, June 22, 2016.
NTTC takes issue with the methodology used in identifying relevant literature for the scoping document. Arguably, the greatest change in TSCA is the mandate of health-based assessment and the inclusion of sensitive and exposed subpopulations in identifying the health risk of chemicals to the American people. Yet, while tribal based risk scenarios are readily available, they are not addressed in the Problem Formulation, and there is no evidence that an attempt was made to include them. Tribes are simply not mentioned, whether it be in the literature search or bibliography, the narrative, or conceptual model. The same holds for ethnic-urban subsistence and rural subpopulations.

RAD POC	Docket #	Action Needed

5	NTTC	1	PESS, Exposure	N/A

The EPA Office of Solid Waste is aware that permitted unlined municipal, and construction and demolition landfills are prevalent in Indian Country. The practice of open burning in burn barrels is widespread, and in Alaska Native villages the entire community wastestream is regularly burned without emissions control under a RCRA permit. Wild foods that the tribes depend on for their diet can be contaminated with HBCD via leachate and smoke, and whole communities can be exposed via inhalation and direct contact with wastes. Extruded and Expanded Polystyrene (XPS and EPS) insulation products are ubiquitous in Alaska and are used in ceilings, floors, interior walls, outside finished exterior walls, foundations and foundation wings, road beds, and more. The construction and demolition waste products, both residential and commercial, are brought to the unlined municipal landfills and dumpsites, or to unlined project-specific dumps. Nearly three-quarters of villages are within one mile of these disposal sites and their diets are dependent on locally hunted, fished, and gathered foods. Over eighty percent of these villages practice open burning, and because the sites are proximate, smoke from these disposal practices is commonly smelled by village residents. Even under the EPA's narrow Conditions of Use requirement, the resultant exposure scenarios for Alaska tribes, as well as Alaska rural residents that comprise more than half the population of the state, are left out. Many tribes are small communities with members being exposed in multiple ways. For example, the same worker who helped in the sawing of EPS board may be the landfill worker that carries the board to the dump and burns it, then goes home to their family where, now part of the community's "bystander" population, they have additional exposures by breathing the smoke, and consuming food and water that is contaminated from leachate.

6	NTTC	1	PESS	N/A
7	NTTC	1	PESS, Exposure	N/A

The following relevant language is excerpted from the Toxic Substances Control Act of 2016, as amended, pertaining to potentially exposed or susceptible subpopulation and to high-priority substances, and from the U.S. EPA Office of Chemical Safety and Pollution Prevention's May 2018 Problem Formulation for Cyclic Aliphatic Bromides Cluster (HBCD) respectively, with emphasis added relevant to the below comments. The term "potentially exposed or susceptible subpopulation" means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly. The Administrator shall designate as a high-priority substance a chemical substance that the Administrator concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator. For HBCD, EPA considers workers, occupational non-users, consumers, and bystanders and certain other groups of individuals who may experience greater exposures than the general population due to proximity to conditions of use to be potentially exposed or susceptible subpopulations. EPA will evaluate whether groups of individuals within the general population may be exposed via pathways that are distinct from the general population due to unique characteristics (e.g., life stage, behaviors, activities, duration) that increase exposure, and whether groups of individuals have heightened susceptibility, and should therefore be considered potentially exposed or susceptible subpopulations for purposes of the risk evaluation.
Activity profiles are not representational. It is known that chlorinated and brominated flame retardants (BFRs) are being released into our environment throughout the world (Bi et al., 2007;35 Kakimoto, Akutsu, Konishi & Tanaka, 200836; Tue et al, 2010;37 Vázquez & Rizo, 2014). Studies such as these include finding brominated flame retardants (BFRs) in multiple biological samples in exposed humans including in the breast milk of mothers living at e-waste recycling sites in China and Vietnam. As noted below, similar practices of openly burning solid waste occur under approved exemption to federal law in Alaska tribal villages, and occur in and near other tribal communities where law enforcement is minimal and underfunded.

8	NTTC	1	PESS, Exposure	N/A
9				

Air Emissions from Open Waste Burning. This study investigated the occurrence of polychlorinated biphenyls (PCBs), and several additive brominated flame retardants (BFRs) in indoor dust and air from two Vietnamese informal e-waste recycling sites (EWRSs) and an urban site in order to assess the relevance of these media for human exposure (Tue et al. 2013). 50 The levels of PBDEs, HBCD, 1,2-bis-(2,4,6-tribromophenoxy)ethane (BTBPE) and decabromodiphenyl ethane (DBDPE) in settled house dust from the EWRSs (130-12,000, 5.4-400, 5.2-620 and 31-1400 ng g(-1), respectively) were significantly higher than in urban house dust but the levels of PCBs (4.8-320 ng g(-1)) were not higher. The levels of PCBs and PBDEs in air at e-waste recycling houses (1000-1800 and 620-720 pg m(-3), respectively), determined using passive sampling, were also higher compared with non-e-waste houses. The composition of BFRs in EWRS samples suggests the influence from high-temperature processes and occurrence of waste materials containing older BFR formulations. Results of daily intake estimation for e-waste recycling workers are in good agreement with the accumulation patterns previously observed in human milk and indicate that dust ingestion contributes a large portion of the PBDE intake (60%-88%), and air inhalation to the low-chlorinated PCB intake (>80% for triCBs) due to their high levels in dust and air, respectively.

10	NTTC	1	General, Exposure	N/A
11	NTTC	1	General	N/A
12	NTTC	1	General, Exposure	N/A

Throughout Asia, non-PBDE BFRs like HBCD, have extensively polluted coastal waters (Isobe, Ogawa, Ramu, Sudaryanto, & Tanabe 2012). They used mussels as a bioindicator, as did studies by the US National Oceanic & Atmospheric Administration of coastal US waters (Isobe et al., 2012), Isobe et al were studying the presence of BFRs, the range throughout Asia, and the levels of concentrations. Among the three HBCD diastereoisomers, α-HBCD was the dominant isomer followed by γ- and β-HBCDs. Concentrations of HBCDs and DBDPE in mussels from Japan and Korea were higher compared to those from the other Asian countries, indicating extensive usage of these non-PBDE BFRs in Japan and Korea. Higher levels of HBCDs and DBDPE than PBDEs were detected in some mussel samples from Japan. The results suggest that environmental pollution by non-PBDE BFRs, especially HBCDs in Japan, is ubiquitous. This study provides baseline information on the contamination status of these non-PBDE BFRs in the coastal waters of Asia. More than 1,500 construction and demolition debris (CDD) landfills operate in the United States (U.S.), and U.S. federal regulations do not require containment features such as low-permeability liners and leachate collection systems for these facilities (Powell, Jain, Smith, Townsend, & Tolaymatl; 2015). Here we evaluate groundwater quality from samples collected in groundwater monitoring networks at 91 unlined, permitted CDD landfills in Florida, U.S. A total of 460,504 groundwater sample results were analyzed, with a median of 10 years of quarterly or semiannual monitoring data per site including more than 400 different chemical constituents. Downgradient concentrations of total dissolved solids, sulfate, chloride, iron, ammonia-nitrogen, and aluminum were greater than upgradient concentrations ($p < 0.05$). At downgradient wells where sulfate concentrations were greater than 150 mg/L (approximately 10% of the maximum dissolved sulfate concentration in water, which suggests the presence of leachate from the landfill), iron and arsenic were detected in 91% and 43% of samples, with median concentrations of 1,900 μg/L and 11 μg/L, respectively. These results show that although health-based standards can be exceeded at unlined CDD landfills, the magnitude of detected chemical concentrations is generally small and reflective of leached minerals from components (wood, concrete, and gypsum drywall) that comprise the bulk of discarded CDD by mass.
In August 2015, EPA published for public comment its TSCA Work Plan Chemical problem formulation and initial assessment documents for the three flame retardant clusters Brominated Bisphenol A (TBBPA), Chlorinated Phosphate Esters (CPE), and Cyclic Aliphatic Bromides (HBCD) (USEPA 2015c). In response NTTC provided written comments to that docket which we recapture here in relevance to problem formulation and risk evaluation under the amended TSCA.
NTTC appreciates EPA's inclusion of fish consumption by subsistence fishers and their children when evaluating exposure pathways for CPE. We specifically highlight EPA's commitment to account for the high-end fish consumption of subsistence fishers—including pregnant women, children and adults—the majority of whom are the tribal population.

13	NTTC	1	Human Health	N/A
14	NTTC	1	Human Health, Exposure	N/A

NTTC agrees with the need to evaluate the hazard endpoints that go beyond cancer risk and include target organ effects, reproductive and developmental effects, and neurotoxicity (U.S. EPA 2015d, p. 32, 34).
In CPE Problem Formulation of 2015, EPA stated it would exclude from further assessment the exposures of birds, terrestrial wildlife, or sediment-dwelling organisms as well as food other than fish. In our comments, NTTC noted its disagreement with EPA's decision as these exclusions fail to account for the subsistence diets of tribal populations, which include these species and other resources that consume these species. In the CPE Problem Formulation, EPA noted that [m]onitoring studies have reported the detection of TCEP in aquatic species, mammalian species, herring gull eggs and pine needles. ...these materials are likely bioavailable and could be observed in a biological matrix." (U.S. EPA 2015d, p. 22). The referenced studies showed detection of CPEs in the breast milk of women in Sweden, Asia, Japan, the Philippines, and Vietnam. These data demonstrate the need for consideration of the natural environment and food resources of tribal populations. Aquatic species, mammalian species and gull eggs are all natural resources upon which tribal populations subsist.

15	NTTC	1	Fate, Exposure	N/A
16	NTTC	1	PESS, Exposure	N/A

Yu et al. (2016) compiled and reviewed existing literature on the contamination status of BFRs in abiotic and biotic environments in China, including polybrominated diphenyl ethers (PBDEs), hexabromocyclododecane, tetrabromobisphenol A and new BFRs. 58 Temporal trends were also summarized and evaluated. Based on this review, it has been concluded that (1) high concentrations of PBDEs were generally related to the e-waste disposal processing, while the spatial distribution pattern of other BFRs was not necessarily in accordance with this; (2) extremely high concentrations of BFRs in indoor dust emphasized the importance of indoor contamination to human body burdens, while more work need to be done to confirm its contribution; (3) PBDEs in electronics dismantling workers were higher compared to the general population, indicating the occupational exposure should be of particular concern; (4) more data are now becoming available for BFRs in aquatic and terrestrial organisms not previously studied, while studies that consider the occurrence of BFRs in organisms of different trophic levels are still of urgent need for evaluating the fate of BFRs in the food web; and (5) limited data showed a decreasing trend for PBDEs, while more data on time trends of BFR contamination in various matrices and locations are still needed before the impact of regulation of BFRs can be assessed.
During problem formulation of HBCD, EPA identified inhalation, dermal and lifetime exposure assessments as data gaps that add uncertainty to EPA's risk assessment of HBCD. NTTC continues to maintain that EPA must include tribal populations in its plans to “conduct additional risk analysis on potential worker, general population, consumer and environmental exposures under the TSCA Existing Chemicals Program” (U.S. EPA, 2015e, p. 11).

17	NTTC	1	PESS, Exposure	N/A

EPA noted that HBCD is a persistent pollutant in environmental media, expected to occur primarily as particulates, which may undergo long range transport, and is highly bioaccumulative with measured fish Bioconcentration factor values of greater than 18,000 (U.S. EPA, 2015e, p. 22). Given this, EPA must consider the impact of consumption by tribal citizens who live in geographic ranges where the majority of industrial-sourced particulates are deposited, who rely on traditional foods of fish and marine mammals which bioaccumulate toxins via fish and algae consumption. Further, on page 24 of the HBCD Problem Formulation, EPA referenced data of HBCD measured in the blubber and liver of various marine mammals; both of these tissues are a staple, consumed in large quantities, in Arctic tribal citizens' diets (U.S. EPA, 2015e, p. 76). Then, regarding bioaccumulation, EPA referenced studies that note the widespread detection and high levels of HBCD in aquatic and terrestrial organisms: invertebrates, fish, birds and their eggs, and marine mammals, all of which are traditional food resources of tribes. Finally, HBCD was detected in breast milk, adipose tissue, blood, and both maternal and umbilical serum (U.S. EPA, 2015e, p. 85). These references to EPA's own work highlights NTTC's principle that EPA must account for tribal populations, especially sensitive infant and child populations, in its risk evaluation of HBCD.

18	NTTC	1	PESS, Exposure	N/A
19	NTTC	1	Exposure	N/A

NTTC supports the EPA's decision for comprehensive studies for many endpoints for all cluster members of the TBB/TBPH cluster. NTTC also supports the EPA's statement of need for comprehensive studies on bioaccumulation of all brominated phthalate cluster (BPC) chemicals. Considering persistence and toxicity data on other brominated flame retardants, bioaccumulation and persistence data are extremely necessary. With the potential for acute and chronic toxicity, reproductive toxicity, and negative health effects on fetal development and endocrine disruption, it is alarming that the U.S. allows continued use of BPC chemicals. NTTC maintains its position that EPA must also consider chemical body burden, in addition to testing all cluster members individually and quantifying major degradation products. With suggested potential of long-term exposure of TBB/TBPH to wildlife, EPA stated that "chronic testing is recommended to address those organisms likely exposed in order to characterize potential population level effects"; and that suggested potential of "exposure and uptake by organisms present in water bodies including aquatic plants thus, hazard and bioaccumulation characterization is needed for these organisms" (U.S. EPA, 2015f, p. 39).60 (TBB/TBPH PF and DNA, 08/158, pp. 39) Therefore, NTTC reiterates that EPA must then also consider the effect of subsistence foods and traditional natural resources on the tribal population. This includes high-level consumption of marine mammals, such as whale, seal, walrus, and sea lion; fish and shellfish, such as salmon, herring, halibut, crab, and mussels; avian species such as duck, geese, and gull; and wildlife such as moose, deer, caribou, and elk.
Since the problem formulations noted above were released in 2015, NTTC has further researched these chemicals in commerce. Brominated flame retardants are found to be a frequent and at times high concentration of indoor dust in houses, apartments, daycare centers, and primary schools, and of the highest concentrations in North America and Europe (Malliari & Kalantzi, 2017). 61 "Results from the studies showed that dust ingestion was the dominant exposure pathway for most studied BFRs compared to indoor air inhalation and dermal contact, especially for infants and toddlers who have higher exposures than older children."

20	NTTC	1	Human Health	N/A
21	NTTC	1	Human Health, Exposure	N/A

HBCD Toxicity testing has detected reproductive, developmental and behavioral effects in animals where exposures are sufficient (Marvin et al. 2011). Recent toxicological advances include a better mechanistic understanding of how HBCD can interfere with the hypothalamicpituitary-thyroid axis, affect normal development, and impact the central nervous system defects.
Fish represents source of nutrients and major dietary vehicle of lipophilic persistent contaminants (Maranghi 2013). The study compared the effects of two legacy and two emerging fish pollutants (Hexabromocyclododecane HBCD; 2,2',4,4'-Tetrabromodiphenyl ether BDE-47; 2,2',4,4',5,5'-Hexachlorobiphenyl PCB-153; 2,3,7,8-Tetrachlorodibenzo-p-doxin TCDD) in juvenile female mice exposed through a salmon based rodent diet for 28 days (dietary doses: HBCD 199 mg/kg bw/day; BDE-47 450 μg/kg bw/day; PCB-153 195 μg/kg bw/day; TCDD 90 ng/kg bw/day). Dose levels were comparable to previously reported developmental Lowest Observed Adverse Effect Levels. None of the treatments elicited signs of overt toxicity, but HBCD increased relative liver weight. All compounds caused changes in liver, thymus and thyroid; spleen was affected by BDE-47 and PCB-153; no effects were seen in uterus and adrenals. Strongest effects in thyroid follicles were elicited by PCB-153, in thymus and liver by BDE-47. HBCD and BDE-47 induced liver fatty changes, but appeared to be less potent in the other tissues. HBCD, BDE-47 and TCDD increased serum testosterone levels and the testosterone/estradiol ratio, suggesting a potential involvement of pathways related to sex steroid biosynthesis and/or metabolism. The results support the role of toxicological studies on juvenile rodents in the hazard characterization of chemicals, due to endocrine and/or immune effects.

22	NTTC	1	Fate, PESS, Exposure	N/A
23	NTTC	1	Fate, PESS, Exposure	N/A

Extensive research indicates significantly concerning characteristics of brominated flame retardants (BFRs). -BFRs are extensively present in environmental and biota samples worldwide, -BFRs are persistent, bioaccumulative, and biomagnified, and -BFRs have high potential toxicity to both ecological environment and human health. Thus BFRs have an even greater potential toxicity to those who more frequently interact with and consume resources from the ecological environment. This is supported by Yu et al. (2016), Wang et al. (2010).
The particular relevance to tribal lifeways as representative of potentially exposed and susceptible subpopulations is especially demonstrated in Yu et al (2016) who, just two years ago, published their review of then existing literature on the contamination status of BFRs in abiotic and biotic environments in China, including polybrominated diphenyl ethers (PBDEs), HBCD, tetrabromobisphenol A (TBBPA), and newer brominated flame retardants (BFRs). Temporal trends were also summarized and evaluated. They concluded that (1) high concentrations of PBDEs were generally related to the e-waste disposal processing, while the spatial distribution pattern of other BFRs was not necessarily in accordance with this; (2) extremely high concentrations of BFRs in indoor dust emphasized the importance of indoor contamination to human body burdens, while more work need to be done to confirm its contribution;(3) PBDEs in electronics dismantling workers were higher compared to the general population, indicating the occupational exposure should be of particular concern; (4) more data are now becoming available for BFRs in aquatic and terrestrial organisms not previously studied, while studies that consider the occurrence of BFRs in organisms of different trophic levels are still of urgent need for evaluating the fate of BFRs in the food web; and (5) limited data showed a decreasing trend for PBDEs, while more data on time trends of BFR contamination in various matrices and locations are still needed before the impact of regulation of BFRs can be assessed.

24	NTTC	1	Fate, PESS, Exposure	N/A

The findings by Wang et al. (2010) are alarming when considered in relation to tribal lifeways and the disposal of electronics in unlined landfills or dumpsites and by open burning. Brominated flame retardants (BFRs) in house dust from the electronic waste (ewaste) recycling and urban areas of South China showed that PBDE levels were comparable to the values found in North America. ...The distinct dust BFR profiles observed in the two studied areas were reflective of activities in these areas (electronics industry vs. e-waste recycling). The estimated daily intakes (EDIs) via house dust were much higher than those via other indoor pathways (air, fish, human milk, and toys). Despite the potentially low deleterious risk of PBDE exposure via house dust as suggested by the hazard quotients, this exposure pathway should be of great concern because of the higher BFR exposures for children and the presence of other BFRs (such as DBDPE) which have not yet been fully investigated. Housing-related exposures, for example. Used furniture and other items containing flame retardants, are gifted to others, purchased at thrift stores or yard sales, and found as free items on sidewalks, roadsides, and at the landfill. Furniture is kept longer than in urban and general populations, often well-passed typical time ranges and simply covered with sheets, blankets or other fabrics. Housing structures are older and smaller, similar to low-income and rural areas, and do not contain air conditioning systems, do not contain air filters, and residents rely on open windows and doors for summer cooling and for venting when cooking and cleaning. Dusting and vacuuming equipment is typically older, lesser quality, or non-existent. Inhalation and ingestion are major exposure pathways and EPA must account for these situations and factors when considering risk.

25	NTTC	1	Fate, PESS, Exposure	N/A

Public infrastructure: The tribal communities we discuss live with significantly outdated public infrastructure, e.g., private wells for drinking water, unplumbed homes, open dumping, kids playing around open dumps. They and others in rural America experience lifestyles much different from the urban centers: recreational swimming in natural water bodies, produce gardening and farming, living near open dumping, unpaved road dust, Arctic entry ways, living all or most of lifetime where they were raised, potlucks and social gatherings, sharing of harvested, grown, and gathered foods. For rural Alaska villages, drinking water, showers, and laundry are accessed at the public watering point, often called the washeteria, where wastewater is handled with only primary treatment. Schreder & La Guardia (2014) studied levels of flame retardants in residential house dust and laundry wastewater as a transport pathway from homes to the outdoor environment in communities near the Columbia River in Washington state (WA), accounting for influent and effluent from two wastewater treatment plants (WWTPs) servicing these communities. Of the 21 brominated and chlorinated compounds, including HBCD, detected in dust, 18 were also detected in laundry wastewater. Comparison of flame retardant levels in WWTP influents to estimates based on laundry wastewater levels indicated that laundry wastewater may be the primary source to these WWTPs.

26	NTTC	1	Fate, PESS, Exposure	N/A

Lack of options in lifestyle. Food is gathered from land and waters locally and regionally. In the 2014 analysis update on subsistence in Alaska, rural residents harvested between 145 and 405 pounds per person per year of wild foods (Fall & Wolfe, 2016).67 The average per person per year amount was about 275 pounds for rural residents versus 19 for urban residents. That was about 0.75 pounds a day per person for rural residents versus 0.05 for urban residents. Costs of store items in Alaska villages and rural areas is prohibitive, often four or more times more expensive than in urban areas, so in general, there are less alternatives to food gathered. There are significantly fewer employment opportunities and higher costs for heating fuel, vehicle fuel, and household basic necessities due to added on cost of shipping items to village. Without incorporating these general profiles, the proposed problem formulations are not relevant to Tribal peoples, a susceptible subpopulation. La Guardia, Hale, Harvey, Mainor, Ciparis (2012) studied in-situ accumulation of HBCD, PBDEs, and several alternative flame-retardants in the bivalve and gastropod. While they found that several alternative brominated flameretardants (BFRs) were being detected in the environment, they noted that contaminant bioavailability is influenced by the organisms' ecology (i.e., route of uptake) and in situ environmental factors. We observed that the filter-feeding bivalve (Corbicula fluminea) and grazing gastropod (Elimia proxima), collected downstream from a textile manufacturing outfall. Maximum levels of total hexabromocyclododecane diastereomers (ΣHBCDs) and those of polybrominated diphenyl ethers (ΣPBDEs) were among the highest reported to date worldwide. While BDE-209 was once thought to be nonbioavailable and resistant to degradation, it was the dominant BFR present and likely debromination products were detected. Contributions of α- and β-HBCD were higher in tissues than sediments, consistent with γ-HBCD bioisomerization. Mollusk bioaccumulation factors were similar between HBCD and PBDEs with 4 to 6 bromines, but factors for TBB, TBPH, and BTBPE were lower. Despite different feeding strategies, the bivalves and gastropods exhibited similar BFR water and sediment accumulation factors.

27	NTTC	1	Fate, PESS, Exposure	N/A
28	NTTC	1	Fate, PESS, Exposure	N/A

In consideration of BFRs effect on flora, for example, Wu, Huang & Zhang (2016) investigation of the accumulation and phytotoxicity of technical hexabromocyclododecane (HBCD) in maize, using young seedlings exposed to solutions of technical HBCD at different concentrations. The results demonstrate HBCD accumulation in both the roots and shoots of the plant, HBCD causing DNA damage, and variances between HBCD diastereoisomers. The uptake kinetics showed that the HBCD concentration reached an apparent equilibrium within 96hr, and the accumulation was much higher in roots than in shoots. HBCD accumulation in maize had a positive linear correlation with the exposure concentration. The accumulation of different diastereoisomers followed the order γ-HBCD>β-HBCD>α-HBCD. Compared with their proportions in the technical HBCD exposure solution, the diastereoisomer contribution increased for β-HBCD and decreased for γ-HBCD in both maize roots and shoots with exposure time, whereas the contribution of α-HBCD increased in roots and decreased in shoots throughout the experimental period. These results suggest the diastereomer-specific accumulation and translocation of HBCD in maize. Inhibitory effects of HBCD on the early development of maize followed the order of germination rate>root biomass≥root elongation>shoot biomass≥shoot elongation. Hydroxyl radical (OH) and histone H2AX phosphorylation (γ-H2AX) were induced in maize by HBCD exposure, indicative of the generation of oxidative stress and DNA double-strand breaks in maize. An OH scavenger inhibited the expression of γ-H2AX foci in both maize roots and shoots, which suggests the involvement of OH generation in the HBCD-induced DNA damage. The results of this study will offer useful information for a more comprehensive assessment of the environmental behavior and toxicity of technical HBCD.
Several studies in the last few years have built on data analysis of BFRs in aquatic and terrestrial species. Sun et al. (2018) measured α-, β-, and γ-HBCDs in three freshwater fish—mud carp, tilapia, and plecostomus—from rivers and an electronic waste (ewaste) recycling site in Pearl River Delta, South China. [Summaries from mutliple studies]

29	EPN_CommentJuly312018	1	RegNex	N/A
30	EPN_CommentJuly312018	1	Exposure, RegNex, Policy	N/A

The Environmental Protection Network (EPN) is providing the following comments on the problem formulations for asbestos, HBCD and carbon tetrachloride, which we find are setting improper precedents for future chemical risk evaluations under the new Chemical Safety Act amendment to TSCA. The final rule states that EPA is given discretion to determine the conditions of use that it will address in its evaluation of a priority chemical, "in order to ensure the agency's focus is on the conditions of use that raise the greatest potential for risk." The final rule mentions excluding de minimis conditions of use or conditions of use that have been adequately addressed by another regulatory agency. The final rule also states that while the statute is ambiguous as to whether the conditions of use should include legacy uses, "in a particular risk evaluation, EPA may consider background exposures from legacy use, associated disposal and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses."
In the following sections of our public comments, the Environmental Protection Network will explain: 1) why the asbestos and HBCD problem formulations should not exclude pathways of exposure to legacy uses; 2) why the asbestos problem formulation should not exclude pathways of exposure regulated under other programs; 3) why the carbon tetrachloride problem formulation should either evaluate the conditions of use now designated as "de minimis" or provide a science-based justification for their exclusion and rationale for not seeking additional information from industry; and 4) why EPA needs to take the lead in addressing workplace risks while consulting with OSHA.

31	EPN_CommentJuly312018	1	Exposure, Policy	N/A
32	EPN_CommentJuly312018	1	Exposure, Policy, RedNex	N/A

1. EPA's Proposed Approach to Risk Evaluation of Exposures Related to Legacy Use is Flawed. The exclusion of "legacy" exposures in the problem formulation documents is particularly flawed for asbestos, and very likely problematic for the cyclic aliphatic bromide cluster chemicals (HBCD) as well. While much of the current risks from asbestos occur among workers involved in asbestos abatement or removal during remodeling, demolition and disposal, there are also risks among maintenance workers with in-place asbestos and auto mechanics performing brake work. Reports published by CDC and IARC strongly suggest that these uses contribute to the widespread release of fibers into the general environment, even with adherence to OSHA and other regulatory limits.
A similar situation likely exists with regard to HBCD. While these chemicals are reportedly no longer manufactured in the U.S., they are still imported and used. There is very likely a substantial amount of legacy materials in place arising from past use in building insulation. Safer Chemicals, Healthy Families estimates that most of the 30,000 to 60,000 metric tons of HBCD used in the U.S. between 1988 and 2010 was used in building insulation and that much of it "will reach the end of its useful life in the years ahead." The potential exposure resulting from the removal of the legacy insulation through demolition, remodeling and disposal, as is the case with asbestos containing materials, may pose risks, and there are no OSHA standards to protect the workers involved in such activities. Therefore, the legacy activities involving HBCD-containing materials must be evaluated if EPA is to successfully fulfill its responsibilities to comprehensively assess and eventually manage the exposures and risks of HBCD under TSCA.

33	Healey_CommentAugust72018	1	General	N/A
34	Healey_CommentAugust72018	1	Other, Policy	N/A

In Massachusetts, the Toxics Use Reduction Institute ("TURI"), created under TURA, Section 6, and the Massachusetts Office of Technical Assistance and Technology ("OTA"), its partner agency, work with Massachusetts businesses to reduce the use of toxic chemicals in the state. TURI and OTA are engaged in on-going work to help Massachusetts businesses and communities reduce their use of toxic solvents including trichloroethylene, perchloroethylene, methylene chloride, 1-bromopropane, and n-methylpyrrolidone, as well as helping businesses adopt safer alternatives to toxic flame retardants, among other efforts. This work to assist Massachusetts businesses and communities complements other regulatory activities within the Commonwealth to protect workers, communities and the environment from these and other toxic chemicals.
Oregon: Oregon has adopted, and is considering, several state-specific statutes and regulations to manage the impacts of toxic and hazardous pollutants that encompass the majority of the Initial Ten TSCA Chemicals. These programs include: • Asbestos emissions, disposal, licensing and certification requirements. From 2011–2015, the CDC reports there were 245 new cases of mesothelioma in Oregon, resulting in 223 deaths. • Air toxics permits and benchmarks for industrial facilities. In addition, Oregon is currently in the process of developing new rules on industrial air emissions that would regulate emissions based on health risks to neighboring communities. The proposed rules will regulate emissions of hundreds of chemicals, including several of the Initial Ten TSCA Chemicals: asbestos, 1-bromopropane, carbon tetrachloride, 1,4 dioxane, tetrachloroethylene, and trichloroethylene. Oregon is relying on federal guidance and expertise to help define potential health risks for communities that are exposed to these emissions and to ensure that communities are protected from cumulative risks from other potential exposure pathways. • Toxics Use and Hazardous Waste Reduction planning requirements, which apply to large and small quantity generators of hazardous waste and Toxic Release Inventory reporters. • State cleanup and remedial actions for hazardous substances, and separate rules for dry cleaning facilities with perchloroethylene (tetrachloroethylene). In addition, legacy contamination from industrial sites is still a potential source of exposure to several of the Initial Ten TSCA Chemicals. The Oregon Health Authority's Environmental Health Assessment Program evaluates potential public health risks from contaminated sites across our state. In the last year alone, the program has been asked to evaluate public health risks from sites where environmental monitoring projects detected at least one of the Initial Ten TSCA Chemicals, including 1,4 dioxane, carbon tetrachloride, methylene chloride, tetrachloroethylene, and/or trichloroethylene. • Oregon adopted the Toxic Free Kids Act in 2015, requiring manufacturers of children's products to report the presence of specific chemicals of concern in products sold in Oregon. Several of the Initial Ten TSCA Chemicals are being reported in that program, including 1,4 dioxane, methylene chloride, tetrachloroethylene, and hexabromocyclododecane. Oregon relies on information from federal agencies to evaluate potential health risks of chemicals of concern for children, to identify new chemicals of concern to add to the reporting list, and to help address cumulative risks from these chemicals through other routes of exposure.

35	Healey_CommentAugust72018	1	Other, Policy	N/A
36	Healey_CommentAugust72018	1	Other, Policy	N/A
37	UCSF_CommentJune252027	2	Exposure	2.2
38	UCSF_CommentJune252036	2	PESS	2.3.5

In addition, under Washington's Children's Safe Products Act, manufacturers whose products contain certain chemicals, like N-Methylpyrrolidone, methylene chloride, tetrachloroethylene, and HBCD, must annually report to Ecology.
With respect to children's products containing HBCD, a flame retardant, Ecology is required to evaluate "potential impacts on human health and the environment resulting from . . . [chemical] exposure" when developing policies and recommendations.
In the Introduction section of the chemical Scope documents [Section 1], EPA states that it "may consider background exposures from legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses." This falls short of the analysis required under Lautenberg TSCA. It is critical that EPA consider ongoing exposures from legacy uses and disposal, and includes these as part of the aggregate exposure assessment. Asbestos and HBCD are two examples of this, as they have enormous volumes in place in buildings and existing infrastructure. The Healthy Building Network estimates there are 66 million-132 million pounds (30,000-60,000 metric tons) of HBCD in insulation in existing buildings —these reservoirs in-place are and will continue to be critical sources of ongoing exposures. HBCD was also used in cars and furniture, which are long-lived consumer items that will continue to contribute to ongoing exposures for years to come.
For example, the prenatal lifestage is the most sensitive to developmental and reproductive toxicants, and women of child-bearing age should be considered as a susceptible sub-population for any chemicals with such hazards. Women of reproductive age are not specifically identified as a potential susceptible sub-population for pigment violet 29, TCE, NMP, PERC, or HBCD, even though EPA will consider reproductive and developmental toxicity hazards for these chemicals.

39	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure	2.2, 2.3.5

Results from the survey related to the 10 priority chemicals are in Table 1, which is divided into two parts. The first part of the table lists chemicals specifically identified by the trainers. The second part lists products they identified, which may contain one or more priority chemicals including:

- Adhesives may contain 1,4-dioxane, 1-BP, carbon tetrachloride, methylene chloride, NMP, PERC, or TCE;
- Coil cleaner may contain 1,4-dioxane, 1-BP, carbon tetrachloride, methylene chloride, NMP, PERC, or TCE;
- Degreaser may contain 1,4-dioxane, 1-BP, PERC, or TCE;
- Flame retardant may contain HBCD;
- Lubricants may contain 1,4-dioxane, methylene chloride, PERC, or TCE;
- Paints and coatings may contain 1,4-dioxane, 1-BP, carbon tetrachloride, NMP, PERC, or pigment violet 29; and
- Soldering flux may contain NMP.

[Table 1: CPWR Pilot Survey Results of Construction Trainers – Common Chemical Hazards Frequency and Control Use, Priority Chemicals, p. 6 of EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU]

40	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure	Executive Summary
41	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Exposure	2.2, 2.3

V. Ongoing Use and Disposal of Chemical Products that are No Longer Being Manufactured Fall Within the TSCA Definition of "Conditions of Use" and Cannot Be Excluded from Risk Evaluations

Among the 10 chemicals are substances, such as asbestos and HBCD, that contribute to ongoing exposure and risk as a result of historical manufacturing and processing activities that have been discontinued. In many cases, the current and foreseeable risks associated with these activities are significant. Nonetheless, the problem formulations, like the scoping documents, take the position that they are outside the scope of risk evaluations. As stated in EPA'S asbestos problem formulation: "In the case of asbestos, legacy uses, associated disposals, and legacy disposals will be excluded from the problem formulation and risk evaluation, as they were in the Scope document. These include asbestos containing materials that remain in older buildings or are part of older products but for which manufacture, processing and distribution in commerce are not currently intended, known or reasonably foreseen. EPA is excluding these activities because EPA generally interprets the mandates under section TSCA § 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacture, processing or distribution is intended, known to be occurring, or reasonably foreseen, rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of conditions of use in that context."

Similarly, the Healthy Building Network estimates there are 66 million- 132 million pounds (30,000-60,000 metric tons) of HBCD in insulation in existing buildings. These ongoing insulation uses are and will continue to be critical sources of ongoing exposures. HBCD is also present in cars and furniture as a flame retardant and its use in these long-lived consumer articles will contribute to ongoing exposures for years to come.29

Footnote:

29 It is unclear whether EPA intends to exclude installed HBCD-containing building and construction materials from its risk evaluation. The problem formulation states that the evaluation will address "commercial/consumer use" of "building/construction materials" but this could be interpreted to apply to materials that are available for use in ongoing construction projects and not those already installed. See Problem Formulation for Cyclic Aliphatic Bromides Cluster (HBCD) (May 2018) at 29.

42	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Exposure	2.2, 2.3
43	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	2.2

Equally important, the disposal of building materials or consumer products containing asbestos or HBCD is an ongoing occurrence as buildings are torn down or remodeled and cars and furniture are replaced. Thus, the resulting releases into the environment and communities comprise a "circumstance . . . under which [these chemicals] are . . . known or reasonably foreseen to be . . . disposed of." As "conditions of use" within the TSCA definition, these activities and the risks they present are likewise required to be addressed in risk evaluations under section 6(b). For both chemicals, the immediate and long-term exposures associated with disposal of in situ building materials and products are likely to be widespread and significant well into the future.30 Footnote: 30 EPA also excludes disposal from the asbestos and HBCD risk evaluations based on its overall determination that the release of chemicals to environmental media should not be addressed under TSCA. Oddly, disposal of HBCD construction and demolition waste is listed as a condition of use EPA plans to address in one part of its problem formulation (page 29) but then identified as an exposure pathway that will not be considered later in the same document (page 52).
The problem formulation for HBCD illustrates this approach. Based on representations by industry, EPA asserts that HBCD use in the production of flame retardants, EPS resins, high impact polystyrene, XPS master batch, motor vehicle upholstery, consumer textiles, and military, institutional and aviation textile applications has ceased. According to EPA, these uses are no longer "intended, known or reasonably foreseen" and therefore do not comprise TSCA "conditions of use" that will be addressed in the HBCD risk evaluation. EPA also indicates that because HBCD is no longer being manufactured in the US, domestic production will likewise not be addressed.

44	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	2.2
45				
46				
47				
48				
49				
50				

EPA has not disclosed the industry communications it is relying on but it appears they are informal and non-binding and have not been verified by the Agency. Nor has EPA indicated that it has contacted all HBCD producers and users to confirm that the uses in question have been fully eliminated. Thus, there is no assurance that these HBCD uses no longer exist and, if so, will not be revived in the future. Indeed, the most likely explanation for the phase-out of previously well-established HBCD uses is the regulatory and public scrutiny HBCD has received, a consideration that could wane in importance in the future, particularly if the risks presented by these uses are not evaluated or restricted by EPA.

Problem Formulation Documents - Public Comments

CCl4 SPECIFIC COMMENTS

#	Submitter	Attachments (#)	Category	Document Section #
1	EPN_CommentJuly312018	1	RegNex	N/A
2	EPN_CommentJuly312018	1	Exposure, RegNex, Policy	N/A

Comment
The Environmental Protection Network (EPN) is providing the following comments on the problem formulations for asbestos, HBCD and carbon tetrachloride, which we find are setting improper precedents for future chemical risk evaluations under the new Chemical Safety Act amendment to TSCA. The final rule states that EPA is given discretion to determine the conditions of use that it will address in its evaluation of a priority chemical, "in order to ensure the agency's focus is on the conditions of use that raise the greatest potential for risk." The final rule mentions excluding de minimis conditions of use or conditions of use that have been adequately addressed by another regulatory agency. The final rule also states that while the statute is ambiguous as to whether the conditions of use should include legacy uses, "in a particular risk evaluation, EPA may consider background exposures from legacy use, associated disposal and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses."
In the following sections of our public comments, the Environmental Protection Network will explain: 1) why the asbestos and HBCD problem formulations should not exclude pathways of exposure to legacy uses; 2) why the asbestos problem formulation should not exclude pathways of exposure regulated under other programs; 3) why the carbon tetrachloride problem formulation should either evaluate the conditions of use now designated as "de minimis" or provide a science-based justification for their exclusion and rationale for not seeking additional information from industry; and 4) why EPA needs to take the lead in addressing workplace risks while consulting with OSHA.

RAD POC	Docket #	Action Needed

3	EPN_CommentJuly312018	1	Policy	2.2.2.1
4	Healey_CommentAugust72018	1	Other, Policy	N/A

3. EPA's Prosposed Approach to Risk Evaluation of Pathways Deemed De minimis is Flawed. In the carbon tetrachloride problem formulation, EPA asserts without justification that it will exclude multiple uses of the chemical (cleaning and degreasing solvents, adhesives and sealants, paints and coatings) because they pose only de minimis risks. This was the only problem formulation that excluded uses because they were deemed de minimis. While the final chemical risk evaluation rule mentions that de minimis uses could be excluded from consideration, no criteria were provided for determining a use that poses de minimis risks for a chronic toxicant. Since carbon tetrachloride is a carcinogen, EPA must document in the problem formulation the carcinogenic risk level used to designate a pathway as posing de minimis risk. In addition, combined low level exposures resulting from multiple uses and sources of a chemical can result in unreasonable risks to particular subpopulations, so EPA must document that co-occurring de minimis pathways were appropriately evaluated in combination and still found to be below the carcinogenic level of concern if people can experience more than one of these pathways at any given time. Further, the carbon tetrachloride problem formulation should justify why EPA is not using its authority to request new testing by industry to better evaluate these de minimis pathways. The new testing provision of the Chemical Safety Act is clear that the administrator must not interpret the lack of exposure information as a lack of exposure or exposure potential and must seek new information to resolve this issue.

With the exception of HBCD and Pigment Violet 29, each of the Initial Ten TSCA Chemicals is listed as either a carcinogen and/or reproductive toxin under California's Safe Drinking Water and Toxic Enforcement Act of 1986 known as "Proposition 65."

5	Healey_CommentAugust72018	1	Other, Policy	N/A

The adverse impacts to California these substances cause are further demonstrated by the following:

• From 2011–2015, the CDC reports there were 1,716 new cases of mesothelioma in California, resulting in 1,318 deaths. Asbestos exposure is the known cause of mesothelioma.

• There have been at least two deaths in California caused by exposure to paint strippers containing methylene chloride since 2012.

• There are 37 sites in California with TCE contamination that have been or are on the National Priorities List (NPL) under the Comprehensive Environment Response, Compensation and Liability Act (CERCLA), 29 with PCE contamination, 6 with asbestos contamination, 10 with 1,4-dioxane contamination, 36 with methylene chloride contamination, and 25 with carbon tetrachloride contamination.

• In 2016, the most current Toxic Release Inventory (TRI) reporting year, a combined total of 2,124,369 pounds of 1,4-dioxane, asbestos, carbon tetrachloride, NMP, PCE and TCE was reported as having been disposed of or released in California.

6	Healey_CommentAugust72018	1	Other, Policy	N/A
7	ACOEMCommentAugust82018	1	General	N/A

Oregon: Oregon has adopted, and is considering, several state-specific statutes and regulations to manage the impacts of toxic and hazardous pollutants that encompass the majority of the Initial Ten TSCA Chemicals. These programs include:

• Asbestos emissions, disposal, licensing and certification requirements. From 2011–2015, the CDC reports there were 245 new cases of mesothelioma in Oregon, resulting in 223 deaths.

• Air toxics permits and benchmarks for industrial facilities. In addition, Oregon is currently in the process of developing new rules on industrial air emissions that would regulate emissions based on health risks to neighboring communities. The proposed rules will regulate emissions of hundreds of chemicals, including several of the Initial Ten TSCA Chemicals: asbestos, 1-bromopropane, carbon tetrachloride, 1,4 dioxane, tetrachloroethylene, and trichloroethylene. Oregon is relying on federal guidance and expertise to help define potential health risks for communities that are exposed to these emissions and to ensure that communities are protected from cumulative risks from other potential exposure pathways.

• Toxics Use and Hazardous Waste Reduction planning requirements, which apply to large and small quantity generators of hazardous waste and Toxic Release Inventory reporters.

• State cleanup and remedial actions for hazardous substances, and separate rules for dry cleaning facilities with perchloroethylene (tetrachloroethylene). In addition, legacy contamination from industrial sites is still a potential source of exposure to several of the Initial Ten TSCA Chemicals. The Oregon Health Authority's Environmental Health Assessment Program evaluates potential public health risks from contaminated sites across our state. In the last year alone, the program has been asked to evaluate public health risks from sites where environmental monitoring projects detected at least one of the Initial Ten TSCA Chemicals, including 1,4 dioxane, carbon tetrachloride, methylene chloride, tetrachloroethylene, and/or trichloroethylene.

• Oregon adopted the Toxic Free Kids Act in 2015, requiring manufacturers of children's products to report the presence of specific chemicals of concern in products sold in Oregon. Several of the Initial Ten TSCA Chemicals are being reported in that program, including 1,4 dioxane, methylene chloride, tetrachloroethylene, and hexabromocyclododecane. Oregon relies on information from federal agencies to evaluate potential health risks of chemicals of concern for children, to identify new chemicals of concern to add to the reporting list, and to help address cumulative risks from these chemicals through other routes of exposure.

The American College of Occupational and Environmental Medicine (ACOEM) is pleased to respond to the EPA's request for comments about its planned chemical evaluation for carbon tetrachloride (CCl_4). EPA is requesting any information from the public on carbon tetrachloride (CCl_4), both domestically and internationally.

ACOEM represents more than 4,000 physicians and other health care professionals specializing in the field of occupational and environmental medicine (OEM). Founded in 1916, ACOEM is the nation's largest medical society dedicated to promoting the health of workers through preventive medicine, clinical care, research, and education. A dynamic group of physicians encompassing specialists in a variety of medical practices is united via the College to develop positions and policies on vital issues relevant to the practice of preventive medicine both within and outside of the workplace.

8	ACOEMCommentAugust82018	1	Exposure	2.3, 2.4
9	ACOEMCommentAugust82018	1	Fate, Human Health	2.3, 2.4
10	Anonymous1August142018	1	General	N/A

We recognize that the literature on the health effects of exposure to carbon tetrachloride (CCl_4) is extensive and that the general public's exposure to this substance has been decreasing. Additionally, ACOEM recognizes that occupationally exposed workers represent a particularly susceptible subpopulation, which continues to have active exposure to CCl_4 and is deserving of special scrutiny. It is estimated that over 58,000 workers are exposed to CCl_4 . OSHA's current permissible exposure limit (PEL) for PCE is 10 ppm for Federal OSHA. We urge EPA to consider all sources of exposure to CCl_4 in potentially exposed workers to assure that cumulative exposures from occupational uses, from ambient air, and/or from drinking water do not exceed an acceptable level.
In addition, ACOEM is concerned about the environmental fate of CCl_4 released into the environment, particularly into ground water where it may linger for many years. Accordingly, ACOEM urges EPA to consider both the cancer and non-cancer health effects resulting from exposure to CCl_4, particularly in occupationally exposed populations, where exposure is likely to be highest. Furthermore, given the troubling worldwide record of environmental CCl_4 contamination, particularly involving groundwater, ACOEM encourages EPA to include in its chemical evaluation the environmental fate and environmental impacts of CCl_4 use, both from intended uses as well as from uses that may be unintended but are reasonably foreseeable.
This is a product long known to have harmful effects and should be banned. We should move on to better and safer products not revisit them.

11	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.2.2, 2.3.5
12	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.2.2, 2.3.5

TSCA also does not adequately address legacy uses of PERC, methylene chloride, carbon tetrachloride, and TCE, as well as bystander exposure to PERC.17 These chemicals are possible or probable human carcinogens and toxic to various organs including the kidney and liver. They are very frequently found in groundwater and soil vapor throughout the City. This "legacy" directly impacts many New Yorkers due to widespread historic (and often current) use and the dense urban environment. These chemicals enter buildings through the soil vapor and frequently cause residents to breathe concentrations that are well above health-based guidance values. However, the extent of this problem is poorly studied and not adequately addressed byany federal acts. Because whole buildings or neighborhoods are sometimes affected, attempting to remediate these chemicals after they have entered into groundwater and soils is expensive and time consuming, and occurs only after building occupants, including children, are exposed to them. In order to prevent human health consequences, and an extraordinary waste of resources, TSCA must regulate them before they are legacy pollution.
By disregarding the risks of legacy uses of all 10 chemicals, most importantly asbestos, PERC, methylene chloride, carbon tetrachloride, and TCE, EPA is excluding from its consideration the means by which many Americans may be exposed to these hazardoussubstances, and undercounting the net risks of exposure for all Americans.

13	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.2.2, 2.3.5

A. The City's Substantive Concerns The Problem Formulations relate to ten different chemicals used across a spectrum of applications and industries, many of which (including, Methylene chloride, Perchloroethene, and Trichloroethene) are used frequently in the City in facilities that, because of our dense urban environment, are co-located in or adjacent to buildings where other people, including sensitive receptors, use the buildings for residential or commercial purposes. Others are currently used with less frequency, but off-gas into the air of buildings because they are present in soil vapor or groundwater (for instance, Carbon tetrachloride and 1-Bromopropane). For instance, dry cleaners are often in residential buildings where children may live or be cared for, or next to schools. Often, these chemicals are used in mixed-use zoning districts where residential and commercial uses are permitted to exist adjacent to or co-located with manufacturing uses. Because of these uses, the City is concerned about the limitations that EPA has set forth in the Problem Formulations that exclude from consideration certain exposure pathways. [Attachment A; comments dated 7/13/18]

14	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.2.2, 2.3.5

New York City has significant soil vapor exposure resulting from extensive use of Carbon tetrachloride, Methylene chloride, Perchloroethene, and Trichloroethene6 within our borders. This contamination results in health consequences not only for workers in the source facility, but also for adjacent or co-located workers, residents, and children. By curtailing TSCA, there will be further opportunities for these chemicals to enter the soil, air, groundwater, and buildings, exposing nearby New Yorkers and requiring unnecessary remediation in the future. [Attachment A; comments dated 7/13/18]

Footnote:

6 Note, while 1-Bromopropane is not often found in City soil vapor. However, if 1-Bromopropane becomes more widely used (e.g., as a replacement solvent for PCE in dry cleaning) then it would likely be more abundant in the soil vapor. The City is hopeful that TSCA risk evaluators will consider the full implications of 1-Bromopropane and its potential for being a future contaminant. Additionally, if chlorinated compounds are replaced with brominated solvents, then other common workplace exposures to brominated solvents will likely increase in the future because the workplace practices are unlikely to change. The City recognizes that in the 1-Bromopropane Problem Formulation, EPA discusses inhalation of the chemical by people occupying businesses co-located with dry cleaners, and states that EPA will consider various issues relating to the chemical's waste, disposal, and use that may impact other non-occupational bystanders. However the Problem Formulation does not specifically discuss the inhalation of 1-Bromopropane in co-located homes.

15	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure	2.2, 2.3.5
16	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General	N/A

Results from the survey related to the 10 priority chemicals are in Table 1, which is divided into two parts. The first part of the table lists chemicals specifically identified by the trainers. The second part lists products they identified, which may contain one or more priority chemicals including: • Adhesives may contain 1,4-dioxane, 1-BP, carbon tetrachloride, methylene chloride, NMP, PERC, or TCE; • Coil cleaner may contain 1,4-dioxane, 1-BP, carbon tetrachloride, methylene chloride, NMP, PERC, or TCE; • Degreaser may contain 1,4-dioxane, 1-BP, PERC, or TCE; • Flame retardant may contain HBCD; • Lubricants may contain 1,4-dioxane, methylene chloride, PERC, or TCE; • Paints and coatings may contain 1,4-dioxane, 1-BP, carbon tetrachloride, NMP, PERC, or pigment violet 29; and • Soldering flux may contain NMP. [Table 1: CPWR Pilot Survey Results of Construction Trainers – Common Chemical Hazards Frequency and Control Use, Priority Chemicals, p. 6 of EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU]
• Six of the 10 chemicals – asbestos (and Libby amphibole asbestos), trichloroethylene (TCE), methylene chloride (MC), carbon tetrachloride (CTA), perchloroethylene (PERC) and 1,4-dioxane – have been assessed under the EPA Integrated Risk Information System (IRIS). The IRIS process is the Agency's authoritative mechanism for reviewing available studies and characterizing the health effects of chemicals. The problem formulations, however, indicate that EPA will revisit the interpretation of studies already evaluated in IRIS using its highly questionable TSCA "systematic review" method that has not been peer reviewed. This may lead to departures from IRIS determinations of the "best available science" and "weight of the evidence." Reopening IRIS findings would harm the public by prolonging uncertainty on issues that have been addressed and resolved through an authoritative and transparent process. In rare cases where significant new data (since the IRIS assessment) are available, the EPA TSCA program should rely on the IRIS program to review, assess, and if appropriate incorporate any new information using a systematic review method that is consistent with the state of the science. (Section X, pages 25-28)

17	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	1

VIII. Where EPA Believes that Particular Conditions of Use Present De Minimis Risks, It Cannot Drop These Uses with no Additional Analysis, But Rather Must Explain and Document Why Their Risks Are Insignificant

The problem formulations also indicate that EPA "expects to be able to reach conclusions about particular conditions of use, hazards or exposure pathways without further analysis" and will not further address them in its risk evaluations.52 For example, EPA indicates that it will devote no further attention to multiple uses of carbon tetrachloride (CTC) that it asserts pose only de minimis risks:

- Because industrial, commercial, and consumer use of such products (solvents for cleaning/degreasing, adhesives/sealants, and paints/coatings) would present only de minimis exposure or otherwise insignificant risk, EPA has determined that these conditions of use do not warrant evaluation, and EPA does not expect to consider or evaluate these conditions of use or associated hazards or exposures in the risk evaluation for carbon tetrachloride.

Footnote:

52 This statement apears in the Introduction to all of the Problem Formulations.

18	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	2.2, 2.4.2
19	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A
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Nowhere has EPA provided general criteria for determining levels of exposure or risk that are "insignificant" for purposes of TSCA risk evaluations. Nor has the Agency explained why it considers carbon tetrachloride-containing solvents with potential consumer, industrial and commercial exposure to be so inconsequential that they can be determined not to present "unreasonable risks" without any product-specific analysis of use and release scenarios.54 Since carbon tetrachloride is a carcinogen, even low concentrations cannot be assumed to be safe without some understanding of the conditions and levels of exposure. Moreover, even if the risk from a specific product is small in itself, multiple products and exposure pathways may result in aggregate levels of exposure that present significant risks to one or more worker or consumer subpopulations. As noted above, TSCA requires EPA to examine chemical risks holistically, taking into account all uses and pathways of exposure, and cannot summarily eliminate an entire class of products from consideration. EPA may have some latitude to devote greater effort to some exposure and risk scenarios than others, but this does not excuse ignoring particular conditions of use based on the unsubstantiated claim that they present de minimis risks.

Footnote:

54 EPA's initial use summary found products with up to 2.5% CTC and SCHF's submission to EPA of publically available product information included products with 1% CTC. See Safer Chemicals, Healthy Families, Environmental Health Strategy Center, Healthy Building Network, Comments to the U.S. Environmental Protection Agency (EPA) on the Scope of its Risk Evaluation for the TSCA Work Plan Chemical: CARBON TETRACHLORIDE (CTC) CAS Reg. No. 56-23-5 (March 15, 2017). This information is not reflected in the problem formulation for CTC.

X. EPA Should Not Revisit Definitive Findings in IRIS Assessments Unless There Are New Data That Inform EPA's Evaluation of the Weight of the Evidence

Six of the 10 chemicals -- asbestos, TCE, MC, CTC, PERC and 1,4-dioxane -- have been assessed under the EPA Integrated Risk Information System (IRIS). The IRIS process is the Agency's authoritative mechanism for reviewing available studies, characterizing the health effects of chemicals and identifying concentrations below which these chemicals are not likely to cause adverse effects. IRIS assessments typically reflect years of work by EPA scientists, multiple rounds of public comment, inter and intraagency consultation, and extensive peer review, often by the Agency's independent Science Advisory Board (SAB) or the National Academy of Sciences (NAS). The IRIS program recently received a favorable review from the NAS.

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Problem Formulation Documents - Public Comments

NMP SPECIFIC COMMENTS

#	Submitter	Attachments (#)	Category	Document Section #
1	Healey_CommentAugust72018	1	General	N/A
2	Healey_CommentAugust72018	1	Other, Policy	N/A
3	Healey_CommentAugust72018	1	Other, Policy	N/A

Comment	RAD POC	Docket #	Action Needed
In Massachusetts, the Toxics Use Reduction Institute ("TURI"), created under TURA, Section 6, and the Massachusetts Office of Technical Assistance and Technology ("OTA"), its partner agency, work with Massachusetts businesses to reduce the use of toxic chemicals in the state. TURI and OTA are engaged in on-going work to help Massachusetts businesses and communities reduce their use of toxic solvents including trichloroethylene, perchloroethylene, methylene chloride, 1-bromopropane, and n-methylpyrrolidone, as well as helping businesses adopt safer alternatives to toxic flame retardants, among other efforts. This work to assist Massachusetts businesses and communities complements other regulatory activities within the Commonwealth to protect workers, communities and the environment from these and other toxic chemicals.			
With the exception of HBCD and Pigment Violet 29, each of the Initial Ten TSCA Chemicals is listed as either a carcinogen and/or reproductive toxin under California's Safe Drinking Water and Toxic Enforcement Act of 1986 known as "Proposition 65."			
The adverse impacts to California these substances cause are further demonstrated by the following: • From 2011–2015, the CDC reports there were 1,716 new cases of mesothelioma in California, resulting in 1,318 deaths. Asbestos exposure is the known cause of mesothelioma. • There have been at least two deaths in California caused by exposure to paint strippers containing methylene chloride since 2012. • There are 37 sites in California with TCE contamination that have been or are on the National Priorities List (NPL) under the Comprehensive Environment Response, Compensation and Liability Act (CERCLA), 29 with PCE contamination, 6 with asbestos contamination, 10 with 1,4-dioxane contamination, 36 with methylene chloride contamination, and 25 with carbon tetrachloride contamination. • In 2016, the most current Toxic Release Inventory (TRI) reporting year, a combined total of 2,124,369 pounds of 1,4-dioxane, asbestos, carbon tetrachloride, NMP, PCE and TCE was reported as having been disposed of or released in California.			

4	Healey_CommentAugust72018	1	Other, Policy	N/A
5	Healey_CommentAugust72018	1	Other, Policy	N/A
6	UCSF_CommentJune252030	2	Exposure, RegNex, Policy	2.2
7	UCSF_CommentJune252036	2	PESS	2.3.5

In addition, under Washington's Children's Safe Products Act, manufacturers whose products contain certain chemicals, like N-Methylpyrrolidone, methylene chloride, tetrachloroethylene, and HBCD, must annually report to Ecology.			
Distric of Columbia: The District of Columbia's Hazardous Waste Management Act includes provisions for toxic chemical source reporting and reduction. Businesses identified by the Standard Industrial Classification (SIC) as the largest generators or within the top 25% of all hazardous waste generators within the District, or that release a toxic chemical subject to regulation are required to file an annual Toxic Release Inventory (TRI) Form R for each TRI-listed chemical it manufactures, processes or otherwise uses in quantities above the threshold reporting quantity. In addition, reporting facilities must prepare and submit a toxic chemical source reduction plan which must be updated every four years. TRI-listed chemicals include the following toxic substances included in the Initial Ten TSCA Chemicals: trichloroethylene, 1-bromopropane and n-methylpyrrolidone.			
Finally, in the exposure assessments for methylene chloride [p. 30 of Scope], N-methylpyrrolidone [pp. 19-20 of Scope] and trichloroethylene [p. 27 of Scope], EPA is proposing to exclude uses it already assessed. We agree that EPA does not need to re-assess these uses; these evaluations have been completed and finalized. However, unless and until such uses are banned, the exposures from these uses continue. Therefore, the new risk evaluations need to consider the contributions of these uses to exposures by using the exposure values from the previous assessments.			
For example, the prenatal lifestage is the most sensitive to developmental and reproductive toxicants, and women of child-bearing age should be considered as a susceptible sub-population for any chemicals with such hazards. Women of reproductive age are not specifically identified as a potential susceptible sub-population for pigment violet 29, TCE, NMP, PERC, or HBCD, even though EPA will consider reproductive and developmental toxicity hazards for these chemicals.			

8	KemiraCommentJuly252018	1	Exposure, Other	B.1.3

In an effort to provide additional information on how NMP may be used in the industrial applications, Kemira is pleased to provide the following comments regarding the Agency's scoping documents description of a reaction medium for polymerization reactions. nMethylpyrrolidone (nMP) is an industrial solvent that is used in a very narrow application. Specifically, it is the preferred sovent for phenothaizine (PTZ), the short-stop chemical for glacial acrylic acid (GAA) and glacial methacryic acid (GMA). In case of an uncontrolled polymerization within the storage tank, the PTZ can be injected in an attempt to stop this reaction and prevent a tank rupture. nMP provides for solution concentrations of up to 35%, is non-flammable and has a relatively low vapor pressure, making it ideal for this application. It is only to be used internally and we see no suitable replacement. There are two usage scenarios for this application. The first, is a 35% by weight PTZ and 65% nMP. The solution is delivered in drums and pumped into a small holding tank, usually located above the GAA storage tank. The handling operator is ideally suited in a chemical resistant jacket, gloves, goggles and a face shield.			

9	KemiraCommentJuly252018	1	Exposure, Other	B.1.3.6

The second usage scenario is to purchase pure nMP and pure PTZ. A solution of approximately 10% PTZ by weight is then manually prepared by adding the PTZ to nMP in a mixing container. The solution is not easily formed so manual breakage of lumps and overnight mixing is required. As with the solution, the handling operator is ideally suited in a chemical resistant jacket, gloves, goggles and a face shield. The prepared solution is then pumped into the holding tank with the same handling precautions as above. Once in the holding tank, the solution may be periodically pumped out to allow servicing of instrumentation and equipment associated with the safety short-stop system. As before, the operator handling the material must be suited in a chemical resistant jacket, gloves, goggles and a face shield. The PTZ solution has a limited shelf life of about 5 years. As a result the solution must be periodically replaced with fresh material. This involves the same pumping and handling operations as above. This use scenario, of a polymerization inhibitor, will not become part of a commercialized finished product where residual nMPs can be measured; therefore no migration to consumer markets of concern is involved. Thank you for your review and consideration of these comments. Feel free to contact us with any questions			

10	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure	2.2, 2.3.5

Results from the survey related to the 10 priority chemicals are in Table 1, which is divided into two parts. The first part of the table lists chemicals specifically identified by the trainers. The second part lists products they identified, which may contain one or more priority chemicals including: • Adhesives may contain 1,4-dioxane, 1-BP, carbon tetrachloride, methylene chloride, NMP, PERC, or TCE; • Coil cleaner may contain 1,4-dioxane, 1-BP, carbon tetrachloride, methylene chloride, NMP, PERC, or TCE; • Degreaser may contain 1,4-dioxane, 1-BP, PERC, or TCE; • Flame retardant may contain HBCD; • Lubricants may contain 1,4-dioxane, methylene chloride, PERC, or TCE; • Paints and coatings may contain 1,4-dioxane, 1-BP, carbon tetrachloride, NMP, PERC, or pigment violet 29; and • Soldering flux may contain NMP. [Table 1: CPWR Pilot Survey Results of Construction Trainers – Common Chemical Hazards Frequency and Control Use, Priority Chemicals, p. 6 of EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU]			

11	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure, Policy, RegNex	2.5
12	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Policy, Exposure	2.2

In addition to air and water, EPA has decided not to consider exposures arising from wastes, specifically stating that "EPA does not expect to include on-site releases to land from industrial non-hazardous and construction/demolition waste landfills". See e.g., Problem Formulation Document for 1-BP at 55, Problem Formulation Document for 1,4-dioxane at 45, Problem Formulation Document for TCE at 56, Problem Formulation Document for methylene chloride at 56, Problem Formulation Document for NMP at 51, Problem Formulation Document for PERC at 62. EPA justifies excluding this pathway from its risk assessment because wastes are primarily regulated under state programs, while also acknowledging that not all states require the same waste disposal protections. Yet, construction workers are routinely involved in handling, storage, and transporting waste materials that potentially contain the priority chemicals. All fourteen building trades unions participate in hazardous waste operations and emergency response (HAZWOPER) activities and Department of Energy site construction and remediation. Removal and disposal tasks can involve cutting, abrading, grinding, demolishing, digging, crushing, loading, and unloading resulting in exposure. It is only by first assessing whether these chemicals pose an unreasonable risk, and then by examining whether the state programs sufficiently address those risks that EPA can satisfy its statutory mandate to decide whether further regulation is required. See §6(a).			
• EPA has proposed to ban certain uses of TCE and N-methylpyrrolidone (NMP) under TSCA section 6(a) based on comprehensive exposure and risk assessments of these uses, including its peer reviewed IRIS assessments on TCE. However, the problem formulations indicate that EPA intends to reopen these completed assessments and delay regulatory action despite serious threats to public health. This is unjustified and unnecessary. EPA should finalize the proposed rules without delay. (Section XI, pages 28-29)			

13	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A
14	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure	2.2, 2.3

XI. EPA Risk Evaluations Should Not Reassess Uses of TCE, MC And NMP That Were Fully Assessed In Its Proposed Section 6(a) Rules for These Chemicals EPA has proposed to ban certain uses of TCE, MC and NMP under section 6(a) of amended TSCA. As the basis for these proposed rules, EPA conducted comprehensive exposure and risk assessments on the targeted uses of the three chemicals and concluded that these uses presented unreasonable risks of injury under TSCA. The EPA assessments were subject to public comment and peer review both during their development and again as part of the rulemaking process. Although the EPA Administrator recently agreed to finalize the proposed MC ban, the problem formulations indicate that EPA will not rely on the completed assessments but will "reassess" the targeted uses for TCE and NMP. We strongly disagree with this approach.			
Finally, as EPA has recognized, some of the industrial hygiene strategies embodied in OSHA standards – such as labels and respirators – are known to be of limited effectiveness in protecting workers and have been required by OSHA to compensate for the lack of effective engineering controls or constraints on its authority, not because they are uniformly protective. For example, in its proposed section 6(a) rules for TCE, MC and NMP, EPA analyzed a universe of 48 studies [84] and concluded that: • [C]onsumers and professionals do not consistently pay attention to labels; consumers and professional users often do not understand label information; consumers and professional users often base a decision to follow label information on previous experience and perceptions of risk; even if consumers and professional users have noticed, read, understood, and believed the information on a hazardous chemical product label, they may not be motivated to follow the label information, instructions, or warnings; and consumers and professional users have varying behavioral responses to warning labels, as shown by mixed results in studies. Footnote: 84 OPPT summarized these studies in a paper entitled: The Effectiveness of Labeling on Hazardous Chemicals and Other Products (March 2016) (Ref. 33 in rulemaking docket).			

15	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure	2.2, 2.3
16	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Exposure	2.2, 2.3
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Similarly, EPA cautioned that "there are many documented limitations to successful implementation of respirators," explaining that: "Not all workers can wear respirators. Individuals with impaired lung function, due to asthma, emphysema, or chronic obstructive pulmonary disease for example, may be physically unable to wear a respirator. Determination of adequate fit and annual fit testing is required for a tight fitting full-face piece respirator to provide the required protection. Also, difficulties associated with selection, fit, and use often render them ineffective in actual application, preventing the assurance of consistent and reliable protection, regardless of the assigned capabilities of the respirator. Individuals who cannot get a good face piece fit, including those individuals whose beards or sideburns interfere with the face piece seal, would be unable to wear tight fitting respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue and reduced work efficiency (63 FR 1156, January 8, 1998). According to OSHA, 'improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health. (63 FR 1189-1190)."			
Because of these considerations, EPA cannot assume that, simply because they are required by OSHA standards, labeling or respirators will in fact provide adequate worker protection and successfully prevent unsafe exposure. Rather, as it did in its proposed rules for MC, TCE and NMP, EPA should explicitly recognize the limitations of these industrial hygiene controls and determine whether risks to workers are unreasonable given that labeling and respirators are often unprotective and unreliable in the real world.			

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Problem Formulation Documents - Public Comments

DCM SPECIFIC COMMENTS

#	Submitter	Attachments (#)	Category	Document Section #
1	APHA	1	Exposure, RegNex	N/A
2	Healey_CommentAugust72018	1	General	N/A

Comment
For example, EPA intends to exclude inhalation of methylene chloride in ambient air. The agency claims that, because methylene chloride is listed as a hazardous air pollutant under the Clean Air Act, this pathway is "adequately assess[ed] and effectively manage[d]" under another statute and need not be considered under TSCA. This is incorrect. EPA manages hazardous air pollutants by requiring source categories to reduce emissions based on what is achievable using certain technologies. The agency does not require source categories to eliminate all emissions, and the remaining emissions can present significant risks. In the case of methylene chloride in ambient air, there is no reason to believe that exposure and risk are effectively managed. As the agency acknowledges, "levels of methylene chloride in the ambient air are widespread and shown to be increasing."
In Massachusetts, the Toxics Use Reduction Institute ("TURI"), created under TURA, Section 6, and the Massachusetts Office of Technical Assistance and Technology ("OTA"), its partner agency, work with Massachusetts businesses to reduce the use of toxic chemicals in the state. TURI and OTA are engaged in on-going work to help Massachusetts businesses and communities reduce their use of toxic solvents including trichloroethylene, perchloroethylene, methylene chloride, 1-bromopropane, and n-methylpyrrolidone, as well as helping businesses adopt safer alternatives to toxic flame retardants, among other efforts. This work to assist Massachusetts businesses and communities complements other regulatory activities within the Commonwealth to protect workers, communities and the environment from these and other toxic chemicals.

RAD POC	Docket #	Action Needed

3	Healey_CommentAugust72018	1	Other, Policy	N/A
4	Healey_CommentAugust72018	1	Other, Policy	N/A
5	Healey_CommentAugust72018	1	Other, Policy	N/A
6	Healey_CommentAugust72018	1	Other, Policy	N/A

California: Because of the significant harm to human health and the environment that the Initial Ten TSCA Chemicals pose, California has implemented regulatory measures including, but not limited to: prohibiting the sale, supply, and manufacturing for use of specified consumer product categories that contain any of the following compounds: TCE, PCE, or methylene chloride; regulating exposure to asbestos in construction work, general industry, shipyards and prohibiting sale of brake pads with asbestiform fibers above .1% weight.
California has proposed regulation of methylene chloride in varnish and paint strippers under its Safer Consumer Products regulations (Cal. Code Regs., tit. 22, § 69501, et seq.).
With the exception of HBCD and Pigment Violet 29, each of the Initial Ten TSCA Chemicals is listed as either a carcinogen and/or reproductive toxin under California's Safe Drinking Water and Toxic Enforcement Act of 1986 known as "Proposition 65."
The adverse impacts to California these substances cause are further demonstrated by the following: • From 2011–2015, the CDC reports there were 1,716 new cases of mesothelioma in California, resulting in 1,318 deaths. Asbestos exposure is the known cause of mesothelioma. • There have been at least two deaths in California caused by exposure to paint strippers containing methylene chloride since 2012. • There are 37 sites in California with TCE contamination that have been or are on the National Priorities List (NPL) under the Comprehensive Environment Response, Compensation and Liability Act (CERCLA), 29 with PCE contamination, 6 with asbestos contamination, 10 with 1,4-dioxane contamination, 36 with methylene chloride contamination, and 25 with carbon tetrachloride contamination. • In 2016, the most current Toxic Release Inventory (TRI) reporting year, a combined total of 2,124,369 pounds of 1,4-dioxane, asbestos, carbon tetrachloride, NMP, PCE and TCE was reported as having been disposed of or released in California.

7	Healey_CommentAugust72018	1	Other, Policy	N/A
8	Healey_CommentAugust72018	1	Other, Policy	N/A

More broadly, the Department regulates the disposal of hazardous waste, including substances included in EPA's Initial Ten TSCA Chemicals. Maryland Department of the Environment regulations generally prohibit the sale, supply, offer for sale, or manufacture for use in the state of adhesives, cleaners, and other products containing methylene chloride, perchloroethylene, or trichloroethylene. Additionally, the Maryland Secretary of Health may declare a substance to be "hazardous material" and establish labeling requirements or, where appropriate, ban the substance. The Secretary has exercised this authority by incorporating by reference Parts 1500 and 1505 of Title 16 of the Code of Federal Regulations (implementing the Federal Hazardous Substances Act). The Secretary is authorized to inspect facilities where hazardous material may be manufactured, processed, packaged, or stored, as well as vehicles used to transport or hold such material.
Oregon: Oregon has adopted, and is considering, several state-specific statutes and regulations to manage the impacts of toxic and hazardous pollutants that encompass the majority of the Initial Ten TSCA Chemicals. These programs include: • Asbestos emissions, disposal, licensing and certification requirements. From 2011–2015, the CDC reports there were 245 new cases of mesothelioma in Oregon, resulting in 223 deaths. • Air toxics permits and benchmarks for industrial facilities. In addition, Oregon is currently in the process of developing new rules on industrial air emissions that would regulate emissions based on health risks to neighboring communities. The proposed rules will regulate emissions of hundreds of chemicals, including several of the Initial Ten TSCA Chemicals: asbestos, 1-bromopropane, carbon tetrachloride, 1,4 dioxane, tetrachloroethylene, and trichloroethylene. Oregon is relying on federal guidance and expertise to help define potential health risks for communities that are exposed to these emissions and to ensure that communities are protected from cumulative risks from other potential exposure pathways. • Toxics Use and Hazardous Waste Reduction planning requirements, which apply to large and small quantity generators of hazardous waste and Toxic Release Inventory reporters. • State cleanup and remedial actions for hazardous substances, and separate rules for dry cleaning facilities with perchloroethylene (tetrachloroethylene). In addition, legacy contamination from industrial sites is still a potential source of exposure to several of the Initial Ten TSCA Chemicals. The Oregon Health Authority's Environmental Health Assessment Program evaluates potential public health risks from contaminated sites across our state. In the last year alone, the program has been asked to evaluate public health risks from sites where environmental monitoring projects detected at least one of the Initial Ten TSCA Chemicals, including 1,4 dioxane, carbon tetrachloride, methylene chloride, tetrachloroethylene, and/or trichloroethylene. • Oregon adopted the Toxic Free Kids Act in 2015, requiring manufacturers of children's products to report the presence of specific chemicals of concern in products sold in Oregon. Several of the Initial Ten TSCA Chemicals are being reported in that program, including 1,4 dioxane, methylene chloride, tetrachloroethylene, and hexabromocyclododecane. Oregon relies on information from federal agencies to evaluate potential health risks of chemicals of concern for children, to identify new chemicals of concern to add to the reporting list, and to help address cumulative risks from these chemicals through other routes of exposure.

9	Healey_CommentAugust72018	1	Other, Policy	N/A
10	Healey_CommentAugust72018	1	RegNex, Exposure	2.4.2.2

In addition, under Washington's Children's Safe Products Act, manufacturers whose products contain certain chemicals, like N-Methylpyrrolidone, methylene chloride, tetrachloroethylene, and HBCD, must annually report to Ecology.
This flaw is also highlighted in the Problem Formulation of the Risk Evaluation for Methylene Chloride. 106 Methylene chloride is a chlorinated solvent commonly used as a metal degreaser, a chemical intermediate, a reaction extraction solvent, a paint stripper, and as a component of adhesives, found in consumer products that can be purchased at local automotive and hardware stores. Methylene chloride exposure can result in serious adverse health effects, and high, short-term exposures can be lethal, with its extreme volatility making it especially dangerous because unsafe airborne concentrations can readily be created through evaporation. As noted in the Problem Formulation, in its IRIS (Integrated Risk Information System) assessment, "EPA concluded that methylene chloride is 'likely to be carcinogenic in humans by all routes of exposure.'"[p. 46] The International Agency for Research on Cancer (IARC) classifies methylene chloride as a possible human carcinogen (Group 2B), and the National Toxicology Program of the U.S. Department of Health and Human Services classifies methylene chloride as "reasonably anticipated to be a human carcinogen." Footnote: 106 Note that on May 10, 2018, EPA announced its intention to finalize a rule making for methylene chloride. See EPA Announces Action on Methylene Chloride, U.S. ENVTL. PROT. AGENCY, https://www.epa.gov/newsreleases/epa-announces-action-methylene-chloride (last accessed Jul. 10, 2018). To our knowledge, EPA has not specified the action it plans to take and it is not clear whether EPA plans to adopt a ban of the chemical and if so, the extent of such ban. However, the Environmental Defense Fund has argued that to protect public health, the final rule should "Ban distribution in commerce and use of methylene chloride for paint and coating removal; extend to both consumer and commercial uses . . . ; not provide exemptions based on training, labeling or use of protective equipment; be finalized and implemented quickly; [and] require full compliance within as short as possible a period." See Richard Denison, Ph.D., Lead Senior Scientist, Environmental Defense Fund, Critical 'blanks' in EPA's methylene chloride announcement need to be filled in if it is to be health protective, May 10, 2018, http://blogs.edf.org/health/2018/05/10/critical-blanks-in-epas-methylene-chloride-announcement-need-to-be-filled-in-if-it-is-to-be-health-protective/ (last accessed Jul. 10, 2018). Home Depot, Loews, and Sherwin-Williams have committed to phasing out methylene chloride and NMP based paint strippers by the end of 2018. See Chemical Watch, Campaigners secure third paint stripper victory with Home Depot," Jun. 20, 2018, https://chemicalwatch.com/67874/campaigners-secure-third-paint-stripper-victory-with-home-depot (last accessed Jul. 10, 2018).

11	Healey_CommentAugust72018	1	RegNex, Exposure	2.3.3
12	ACOEM_CommentAugust82018	1	General	N/A

Methylene chloride is a widespread contaminant in our environment. For example, the problem formulation notes that "[d]ata compiled between 1992 and 2001 from NAWQA [the U.S. Geological Survey's National Water Quality Assessment Program] showed methylene chloride to be found in 6% of all ground water and surface water samples, with occurrences more common in surface water. Methylene chloride was detected in 20% of sediment samples in the [EPA] STORET database." [p. 36] And yet, EPA plans to exclude exposure pathways for methylene chloride that allegedly are addressed under other statutes although these pathways have been identified for regulation precisely because they are known or suspected to pose a serious concern. For example, EPA plans to exclude from consideration: (i) "stationary source releases of methylene chloride to ambient air," as methylene chloride is regulated as a hazardous air pollutant (HAP) under the Clean Air Act; and (ii) exposures through drinking water because these are regulated under the Safe Drinking Water Act. EPA also plans to exclude from consideration "methylene chloride-based extraction solvents for oils, waxes, fats, spices, and hops" because they "meet the definition of food additive" under the Federal Food, Drug and Cosmetic Act, and so would ignore potentially significant exposure pathways. By excluding consideration of exposures to methylene chloride through drinking water and other pathways of chronic exposure, it will not be possible for EPA to conduct an adequate risk evaluation for methylene chloride under Section 6 of TSCA. Through this misguided approach of ignoring uses that are subject to other regulatory schemes, EPA has essentially eliminated from consideration those pathways that Congress has prioritized for regulation to date.
The American College of Occupational and Environmental Medicine (ACOEM) is pleased to respond to the EPA's request for comments about its planned chemical evaluation for methylene chloride. EPA is requesting any information from the public on methylene chloride both domestically and internationally. ACOEM represents more than 4,000 physicians and other health care professionals specializing in the field of occupational and environmental medicine (OEM). Founded in 1916, ACOEM is the nation's largest medical society dedicated to promoting the health of workers through preventive medicine, clinical care, research, and education. A dynamic group of physicians encompassing specialists in a variety of medical practices is united via the College to develop positions and policies on vital issues relevant to the practice of preventive medicine both within and outside of the workplace.

13	ACOEM_CommentAugust82018	1	Exposure, Human Health	2.3, 2.4
14	ACOEM_CommentAugust82018	1	Exposure, Human Health	2.3, 2.4
15	UCSF_CommentJune252030	2	Exposure, RegNex, Policy	2.2

We recognize that the literature on the health effects of exposure to methylene chloride is extensive. Additionally, ACOEM recognizes that occupationally exposed workers represent a particularly susceptible subpopulation, deserving of special scrutiny. We further recognize that OSHA's current rule for exposure to methylene chloride for general industry as well as the maritime and construction trades is likely to be protective for non-cancer health effects, if followed by employers. However, the current PEL for methylene chloride (25 ppm, or 87 mg/cu m, as an 8-hour time-weighted average) would theoretically expose a worker to as much 480 mg of methylene chloride per day, assuming a breathing rate of 10 cu meters per 8-hour shift and an absorption factor of about 55%. Exposures in this range over a lifetime would impose on such exposed workers an incremental cancer risk exceeding one chance in a hundred, taking account of the current cancer potency estimates for methylene chloride.
In addition, ACOEM is concerned about the multiple reports of fatal occupational exposures to methylene chloride, resulting from employers and employees failing to adhere to current OSHA rules and standard practices for the safe use of methylene chloride in paint-stripping and other refinishing operations. ACOEM would like to see a sharp reduction in exposures to methylene chloride in workers and members of the general population who strip paint. Accordingly, ACOEM urges EPA to consider both the cancer and non-cancer health effects resulting from exposure to methylene chloride, particularly in occupationally exposed populations, where exposure is likely to be highest.
Finally, in the exposure assessments for methylene chloride [p. 30 of Scope], N-methylpyrrolidone [pp. 19-20 of Scope] and trichloroethylene [p. 27 of Scope], EPA is proposing to exclude uses it already assessed. We agree that EPA does not need to re-assess these uses; these evaluations have been completed and finalized. However, unless and until such uses are banned, the exposures from these uses continue. Therefore, the new risk evaluations need to consider the contributions of these uses to exposures by using the exposure values from the previous assessments.

16	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.2.2, 2.3.5
17	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.2.2, 2.3.5

TSCA also does not adequately address legacy uses of PERC, methylene chloride, carbon tetrachloride, and TCE, as well as bystander exposure to PERC.17 These chemicals are possible or probable human carcinogens and toxic to various organs including the kidney and liver. They are very frequently found in groundwater and soil vapor throughout the City. This "legacy" directly impacts many New Yorkers due to widespread historic (and often current) use and the dense urban environment. These chemicals enter buildings through the soil vapor and frequently cause residents to breathe concentrations that are well above health-based guidance values. However, the extent of this problem is poorly studied and not adequately addressed byany federal acts. Because whole buildings or neighborhoods are sometimes affected, attempting to remediate these chemicals after they have entered into groundwater and soils is expensive and time consuming, and occurs only after building occupants, including children, are exposed to them. In order to prevent human health consequences, and an extraordinary waste of resources, TSCA must regulate them before they are legacy pollution.
By disregarding the risks of legacy uses of all 10 chemicals, most importantly asbestos, PERC, methylene chloride, carbon tetrachloride, and TCE, EPA is excluding from its consideration the means by which many Americans may be exposed to these hazardoussubstances, and undercounting the net risks of exposure for all Americans.

18	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.2.2, 2.3.5

A. The City's Substantive Concerns The Problem Formulations relate to ten different chemicals used across a spectrum of applications and industries, many of which (including, Methylene chloride, Perchloroethene, and Trichloroethene) are used frequently in the City in facilities that, because of our dense urban environment, are co-located in or adjacent to buildings where other people, including sensitive receptors, use the buildings for residential or commercial purposes. Others are currently used with less frequency, but off-gas into the air of buildings because they are present in soil vapor or groundwater (for instance, Carbon tetrachloride and 1-Bromopropane). For instance, dry cleaners are often in residential buildings where children may live or be cared for, or next to schools. Often, these chemicals are used in mixed-use zoning districts where residential and commercial uses are permitted to exist adjacent to or co-located with manufacturing uses. Because of these uses, the City is concerned about the limitations that EPA has set forth in the Problem Formulations that exclude from consideration certain exposure pathways. [Attachment A; comments dated 7/13/18]

19	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.2.2, 2.3.5

New York City has significant soil vapor exposure resulting from extensive use of Carbon tetrachloride, Methylene chloride, Perchloroethene, and Trichloroethene6 within our borders. This contamination results in health consequences not only for workers in the source facility, but also for adjacent or co-located workers, residents, and children. By curtailing TSCA, there will be further opportunities for these chemicals to enter the soil, air, groundwater, and buildings, exposing nearby New Yorkers and requiring unnecessary remediation in the future. [Attachment A; comments dated 7/13/18]

Footnote:

6 Note, while 1-Bromopropane is not often found in City soil vapor. However, if 1-Bromopropane becomes more widely used (e.g., as a replacement solvent for PCE in dry cleaning) then it would likely be more abundant in the soil vapor. The City is hopeful that TSCA risk evaluators will consider the full implications of 1-Bromopropane and its potential for being a future contaminant. Additionally, if chlorinated compounds are replaced with brominated solvents, then other common workplace exposures to brominated solvents will likely increase in the future because the workplace practices are unlikely to change. The City recognizes that in the 1-Bromopropane Problem Formulation, EPA discusses inhalation of the chemical by people occupying businesses co-located with dry cleaners, and states that EPA will consider various issues relating to the chemical's waste, disposal, and use that may impact other non-occupational bystanders. However the Problem Formulation does not specifically discuss the inhalation of 1-Bromopropane in co-located homes.

20	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure, PESS	2.2, 2.3.5
21	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure	2.2, 2.3.5

The wide variety of chemicals to which construction workers are exposed is evident from a pilot study completed by CPWR - The Center for Construction Research and Training in January 2018. The pilot study asked 196 safety and health trainers from four different construction unions to identify common chemical hazards encountered in their trades. The trainers identified 63 different common chemical hazards in their trade, including some of the priority chemicals. The results were instructive, as they revealed not only the large numbers and wide range of chemicals which construction workers regularly encounter, but they showed that even these well-informed trainers did not necessarily know which specific chemicals are present in the products they use. For example, while almost two thirds of trainers listed adhesives as a common hazard, less than one fifth reported 1-bromopropane, methylene chloride, perchloroethylene, or trichloroethylene as a common hazard, even though these chemicals are known components of some adhesives.
Results from the survey related to the 10 priority chemicals are in Table 1, which is divided into two parts. The first part of the table lists chemicals specifically identified by the trainers. The second part lists products they identified, which may contain one or more priority chemicals including: • Adhesives may contain 1,4-dioxane, 1-BP, carbon tetrachloride, methylene chloride, NMP, PERC, or TCE; • Coil cleaner may contain 1,4-dioxane, 1-BP, carbon tetrachloride, methylene chloride, NMP, PERC, or TCE; • Degreaser may contain 1,4-dioxane, 1-BP, PERC, or TCE; • Flame retardant may contain HBCD; • Lubricants may contain 1,4-dioxane, methylene chloride, PERC, or TCE; • Paints and coatings may contain 1,4-dioxane, 1-BP, carbon tetrachloride, NMP, PERC, or pigment violet 29; and • Soldering flux may contain NMP. [Table 1: CPWR Pilot Survey Results of Construction Trainers – Common Chemical Hazards Frequency and Control Use, Priority Chemicals, p. 6 of EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU]

22	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure	2.2, 2.3.5

Results from the survey related to the 10 priority chemicals are in Table 1, which is divided into two parts. The first part of the table lists chemicals specifically identified by the trainers. The second part lists products they identified, which may contain one or more priority chemicals including:

- Adhesives may contain 1,4-dioxane, 1-BP, carbon tetrachloride, methylene chloride, NMP, PERC, or TCE;
- Coil cleaner may contain 1,4-dioxane, 1-BP, carbon tetrachloride, methylene chloride, NMP, PERC, or TCE;
- Degreaser may contain 1,4-dioxane, 1-BP, PERC, or TCE;
- Flame retardant may contain HBCD;
- Lubricants may contain 1,4-dioxane, methylene chloride, PERC, or TCE;
- Paints and coatings may contain 1,4-dioxane, 1-BP, carbon tetrachloride, NMP, PERC, or pigment violet 29; and
- Soldering flux may contain NMP.

[Table 1: CPWR Pilot Survey Results of Construction Trainers – Common Chemical Hazards Frequency and Control Use, Priority Chemicals, p. 6 of EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU]

23	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure, Policy, RegNex	2.5
24				

In addition to air and water, EPA has decided not to consider exposures arising from wastes, specifically stating that "EPA does not expect to include on-site releases to land from industrial non-hazardous and construction/demolition waste landfills". See e.g., Problem Formulation Document for 1-BP at 55, Problem Formulation Document for 1,4-dioxane at 45, Problem Formulation Document for TCE at 56, Problem Formulation Document for methylene chloride at 56, Problem Formulation Document for NMP at 51, Problem Formulation Document for PERC at 62. EPA justifies excluding this pathway from its risk assessment because wastes are primarily regulated under state programs, while also acknowledging that not all states require the same waste disposal protections. Yet, construction workers are routinely involved in handling, storage, and transporting waste materials that potentially contain the priority chemicals. All fourteen building trades unions participate in hazardous waste operations and emergency response (HAZWOPER) activities and Department of Energy site construction and remediation. Removal and disposal tasks can involve cutting, abrading, grinding, demolishing, digging, crushing, loading, and unloading resulting in exposure. It is only by first assessing whether these chemicals pose an unreasonable risk, and then by examining whether the state programs sufficiently address those risks that EPA can satisfy its statutory mandate to decide whether further regulation is required. See §6(a).

25	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General	N/A
26	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Policy, Exposure	2.2

• Six of the 10 chemicals – asbestos (and Libby amphibole asbestos), trichloroethylene (TCE), methylene chloride (MC), carbon tetrachloride (CTA), perchloroethylene (PERC) and 1,4-dioxane – have been assessed under the EPA Integrated Risk Information System (IRIS). The IRIS process is the Agency's authoritative mechanism for reviewing available studies and characterizing the health effects of chemicals. The problem formulations, however, indicate that EPA will revisit the interpretation of studies already evaluated in IRIS using its highly questionable TSCA "systematic review" method that has not been peer reviewed. This may lead to departures from IRIS determinations of the "best available science" and "weight of the evidence." Reopening IRIS findings would harm the public by prolonging uncertainty on issues that have been addressed and resolved through an authoritative and transparent process. In rare cases where significant new data (since the IRIS assessment) are available, the EPA TSCA program should rely on the IRIS program to review, assess, and if appropriate incorporate any new information using a systematic review method that is consistent with the state of the science. (Section X, pages 25-28)
• EPA has proposed to ban certain uses of TCE and N-methylpyrrolidone (NMP) under TSCA section 6(a) based on comprehensive exposure and risk assessments of these uses, including its peer reviewed IRIS assessments on TCE. However, the problem formulations indicate that EPA intends to reopen these completed assessments and delay regulatory action despite serious threats to public health. This is unjustified and unnecessary. EPA should finalize the proposed rules without delay. (Section XI, pages 28-29)

27	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Human Health	2.4.2
28	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A

MC. MC is a known human neurotoxicant, associated with depression of the central nervous system, and severe dose-dependent neurotoxic effects including headaches, slowed reaction time, decreased alertness, impaired movements, loss of consciousness, coma, seizures, and death. (It has been shown in animal studies to cross the placenta, and in humans it has been detected in breast milk.) Yet, the chemical has not been adequately tested for developmental neurotoxicity. This is especially alarming given the widespread use and population exposure to this deadly neurotoxic chemical. Chemicals that are neurotoxic should be presumed to be developmentally neurotoxic. That is, compared with adult exposures, they are much more damaging and at much lower levels when exposures take place during early fetal development. The failure to test and appropriately regulate these chemicals has led to debilitating neurodevelopmental disorders such as autism, learning deficits, and behavioral problems – all with disastrous impacts on affected individuals, families, and society.
X. EPA Should Not Revisit Definitive Findings in IRIS Assessments Unless There Are New Data That Inform EPA's Evaluation of the Weight of the Evidence Six of the 10 chemicals -- asbestos, TCE, MC, CTC, PERC and 1,4-dioxane -- have been assessed under the EPA Integrated Risk Information System (IRIS). The IRIS process is the Agency's authoritative mechanism for reviewing available studies, characterizing the health effects of chemicals and identifying concentrations below which these chemicals are not likely to cause adverse effects. IRIS assessments typically reflect years of work by EPA scientists, multiple rounds of public comment, inter and intraagency consultation, and extensive peer review, often by the Agency's independent Science Advisory Board (SAB) or the National Academy of Sciences (NAS). The IRIS program recently received a favorable review from the NAS.

29	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A
30	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Exposure	2.3

XI. EPA Risk Evaluations Should Not Reassess Uses of TCE, MC And NMP That Were Fully Assessed In Its Proposed Section 6(a) Rules for These Chemicals

EPA has proposed to ban certain uses of TCE, MC and NMP under section 6(a) of amended TSCA. As the basis for these proposed rules, EPA conducted comprehensive exposure and risk assessments on the targeted uses of the three chemicals and concluded that these uses presented unreasonable risks of injury under TSCA. The EPA assessments were subject to public comment and peer review both during their development and again as part of the rulemaking process. Although the EPA Administrator recently agreed to finalize the proposed MC ban, the problem formulations indicate that EPA will not rely on the completed assessments but will "reassess" the targeted uses for TCE and NMP. We strongly disagree with this approach.

Second, a number of the OSHA standards that apply to chemicals subject to the first 10 risk evaluations were developed many years ago and do not reflect current data and scientific understanding of the health effects of the regulated chemicals.81 Thus, the levels of exposure allowed by these standards may be unsafe when evaluated using the best available science.

Footnote:

81 OSHA has two types of standards. Under section 6(a) of the OSH Act, OSHA adopted hundreds of PELs in 1971 that were, at that time, considered national consensus standards. They have not been updated since and are based on science from the 1960s or earlier. Since 1971, OSHA has regulated only about 40 chemicals under section 6(b). These more comprehensive standards are based on thorough evaluation of health effects and a determination that risks are significant. OSHA has 6(b) standards regulating only asbestos and MC. It has PELs (adopted under 6(a)) for PERC and TCE but not for the other 10 chemicals. In the case of both asbestos and MC, OSHA's published Federal Register preambles found that even at the revised PEL, employees continued to be exposed to significant risks i.e., risks above 1/1000 – OSHA's definition of significant risk.

31	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Exposure	2.2, 2.3
32	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Exposure	2.2, 2.3

Third, OSHA does not cover all workers. It only covers private sector employees of employers. It does not cover employees of federal, state or local governments. These workers might include building maintenance people exposed to asbestos, hospital workers exposed to PERC when laundering linens or other supplies, etc. OSHA also does not cover independent contractors. In the construction sector, many people performing remodeling work, such as stripping paint and otherwise using MC, or removing asbestos insulation are independent. These workers have no OSHA protection. So even if OSHA standards were adequately protective of the workers they covered, there would still be a need for EPA to act under TSCA to make sure all workers had an equivalent level of protection.

Fourth, there is no basis for EPA to assume across-the-board compliance with OSHA standards. As the Agency pointed out in its proposed section 6(a) rule for MC paint removal products, exposures above the OSHA limit have been well documented.82 To determine actual workplace exposures, we encourage EPA to obtain and review all the data gathered by law under OSHA's Access standard, 29 CFR 1910.1020 which "provide[s] employees and their designated representatives a right of access to relevant exposure and medical records; and to provide representatives of the Assistant Secretary a right of access to these records in order to fulfill responsibilities under the Occupational Safety and Health Act."83 (1910.1020(a)). This would provide a basis for comparing actual exposures to OSHA standards and, for specific chemicals, determine whether and to what extent OSHA standards reliably limit exposure. While these data will provide a valuable snapshot of exposures, it should be kept in mind that OSHA exposure monitoring data is not systematic or comprehensive, and therefore may not be representative of workplace chronic or peak exposures that are likely to be missed with snapshot monitoring.

Footnotes:

82 Studies referenced by EPA found widespread non-compliance with the OSHA MC workplace standard during paint and coating removal, resulting in MC exposures above the OSHA standard, despite the mandatory nature of the OSHA requirements. 82 FR 7405 (Ref. 70)

83 These data include:

• "Environmental (workplace) monitoring or measuring of a toxic substance or harmful physical agent, including personal, area, grab, wipe, or other form of sampling, as well as related collection and analytical methodologies, calculations, and other background data relevant to interpretation of the results obtained" (1910.1020(c)(5)(i)); and,

• "Biological monitoring results which directly assess the absorption of a toxic substance or harmful physical agent by body systems (e.g., the level of a chemical in the blood, urine, breath, hair, fingernails, etc.)" (excluding drug and alcohol testing) 1910.1020(c)(5)(ii).

For example, the OSHA standard for methylene chloride can be found at 29 CFR 1910.1052, which describes details of mandatory exposure monitoring, employee notification requirements, and long-term retention of the monitoring results. Under OSHA's Access standard, 29 CFR 1910.1020 (D)(7)(ii), employers must retain these records for 30 years.

33	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure	2.2, 2.3

Finally, as EPA has recognized, some of the industrial hygiene strategies embodied in OSHA standards – such as labels and respirators – are known to be of limited effectiveness in protecting workers and have been required by OSHA to compensate for the lack of effective engineering controls or constraints on its authority, not because they are uniformly protective. For example, in its proposed section 6(a) rules for TCE, MC and NMP, EPA analyzed a universe of 48 studies [84] and concluded that: • [C]onsumers and professionals do not consistently pay attention to labels; consumers and professional users often do not understand label information; consumers and professional users often base a decision to follow label information on previous experience and perceptions of risk; even if consumers and professional users have noticed, read, understood, and believed the information on a hazardous chemical product label, they may not be motivated to follow the label information, instructions, or warnings; and consumers and professional users have varying behavioral responses to warning labels, as shown by mixed results in studies.

Footnote:

84 OPPT summarized these studies in a paper entitled: The Effectiveness of Labeling on Hazardous Chemicals and Other Products (March 2016) (Ref. 33 in rulemaking docket).

EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure	2.2, 2.3
EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Exposure	2.2, 2.3

Similarly, EPA cautioned that "there are many documented limitations to successful implementation of respirators," explaining that: "Not all workers can wear respirators. Individuals with impaired lung function, due to asthma, emphysema, or chronic obstructive pulmonary disease for example, may be physically unable to wear a respirator. Determination of adequate fit and annual fit testing is required for a tight fitting full-face piece respirator to provide the required protection. Also, difficulties associated with selection, fit, and use often render them ineffective in actual application, preventing the assurance of consistent and reliable protection, regardless of the assigned capabilities of the respirator. Individuals who cannot get a good face piece fit, including those individuals whose beards or sideburns interfere with the face piece seal, would be unable to wear tight fitting respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue and reduced work efficiency (63 FR 1156, January 8, 1998). According to OSHA, 'improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health. (63 FR 1189-1190)."
Because of these considerations, EPA cannot assume that, simply because they are required by OSHA standards, labeling or respirators will in fact provide adequate worker protection and successfully prevent unsafe exposure. Rather, as it did in its proposed rules for MC, TCE and NMP, EPA should explicitly recognize the limitations of these industrial hygiene controls and determine whether risks to workers are unreasonable given that labeling and respirators are often unprotective and unreliable in the real world.

Problem Formulation Documents - Public Comments

TCE SPECIFIC COMMENTS

#	Submitter	Attachments (#)	Category
1	Healey_CommentAugust72018	1	General
2	Healey_CommentAugust72018	1	Other, Policy
3	Healey_CommentAugust72018	1	Other, Policy

Document Section #
N/A
N/A
N/A

Comment
In Massachusetts, the Toxics Use Reduction Institute ("TURI"), created under TURA, Section 6, and the Massachusetts Office of Technical Assistance and Technology ("OTA"), its partner agency, work with Massachusetts businesses to reduce the use of toxic chemicals in the state. TURI and OTA are engaged in on-going work to help Massachusetts businesses and communities reduce their use of toxic solvents including trichloroethylene, perchloroethylene, methylene chloride, 1-bromopropane, and n-methylpyrrolidone, as well as helping businesses adopt safer alternatives to toxic flame retardants, among other efforts. This work to assist Massachusetts businesses and communities complements other regulatory activities within the Commonwealth to protect workers, communities and the environment from these and other toxic chemicals.
California: Because of the significant harm to human health and the environment that the Initial Ten TSCA Chemicals pose, California has implemented regulatory measures including, but not limited to: prohibiting the sale, supply, and manufacturing for use of specified consumer product categories that contain any of the following compounds: TCE, PCE, or methylene chloride; regulating exposure to asbestos in construction work, general industry, shipyards and prohibiting sale of brake pads with asbestiform fibers above .1% weight.
With the exception of HBCD and Pigment Violet 29, each of the Initial Ten TSCA Chemicals is listed as either a carcinogen and/or reproductive toxin under California's Safe Drinking Water and Toxic Enforcement Act of 1986 known as "Proposition 65."

RAD POC	Docket #	Action Needed

4	Healey_CommentAugust72018	1	Other, Policy
5	Healey_CommentAugust72018	1	Other, Policy

N/A
N/A

The adverse impacts to California these substances cause are further demonstrated by the following: • From 2011–2015, the CDC reports there were 1,716 new cases of mesothelioma in California, resulting in 1,318 deaths. Asbestos exposure is the known cause of mesothelioma. • There have been at least two deaths in California caused by exposure to paint strippers containing methylene chloride since 2012. • There are 37 sites in California with TCE contamination that have been or are on the National Priorities List (NPL) under the Comprehensive Environment Response, Compensation and Liability Act (CERCLA), 29 with PCE contamination, 6 with asbestos contamination, 10 with 1,4-dioxane contamination, 36 with methylene chloride contamination, and 25 with carbon tetrachloride contamination. • In 2016, the most current Toxic Release Inventory (TRI) reporting year, a combined total of 2,124,369 pounds of 1,4-dioxane, asbestos, carbon tetrachloride, NMP, PCE and TCE was reported as having been disposed of or released in California.
Maine: Under the Maine Priority Toxic Chemical Use Reduction law, 38 Maine Revised Statutes ("M.R.S.") §§ 2331-2330, and corresponding rule, 06-096 Code of Maine Rules ("CMR") ch. 82, commercial and industrial facilities using more than 1,000 pounds/year of a priority toxic chemical listed in Maine's rule, 06-096 CMR ch. 81, must report their usage of the chemical and must develop a pollution prevention plan, which must be updated every two years. Maine has identified five chemicals as priority toxic chemicals under this law, two of which are on the list of Initial Ten TSCA Chemicals—perchloroethylene and trichloroethylene.

6	Healey_CommentAugust72018	1	Other, Policy
7	Healey_CommentAugust72018	1	Other, Policy

N/A
N/A

More broadly, the Department regulates the disposal of hazardous waste, including substances included in EPA's Initial Ten TSCA Chemicals. Maryland Department of the Environment regulations generally prohibit the sale, supply, offer for sale, or manufacture for use in the state of adhesives, cleaners, and other products containing methylene chloride, perchloroethylene, or trichloroethylene. Additionally, the Maryland Secretary of Health may declare a substance to be "hazardous material" and establish labeling requirements or, where appropriate, ban the substance. The Secretary has exercised this authority by incorporating by reference Parts 1500 and 1505 of Title 16 of the Code of Federal Regulations (implementing the Federal Hazardous Substances Act). The Secretary is authorized to inspect facilities where hazardous material may be manufactured, processed, packaged, or stored, as well as vehicles used to transport or hold such material.
New York has spent millions of dollars cleaning up tetrachloroethylene (perc) and trichloroethylene at hazardous waste sites.

8	Healey_CommentAugust72018	1	Other, Policy
9	Healey_CommentAugust72018	1	Other, Policy

N/A
N/A

Oregon: Oregon has adopted, and is considering, several state-specific statutes and regulations to manage the impacts of toxic and hazardous pollutants that encompass the majority of the Initial Ten TSCA Chemicals. These programs include: • Asbestos emissions, disposal, licensing and certification requirements. From 2011–2015, the CDC reports there were 245 new cases of mesothelioma in Oregon, resulting in 223 deaths. • Air toxics permits and benchmarks for industrial facilities. In addition, Oregon is currently in the process of developing new rules on industrial air emissions that would regulate emissions based on health risks to neighboring communities. The proposed rules will regulate emissions of hundreds of chemicals, including several of the Initial Ten TSCA Chemicals: asbestos, 1-bromopropane, carbon tetrachloride, 1,4 dioxane, tetrachloroethylene, and trichloroethylene. Oregon is relying on federal guidance and expertise to help define potential health risks for communities that are exposed to these emissions and to ensure that communities are protected from cumulative risks from other potential exposure pathways. • Toxics Use and Hazardous Waste Reduction planning requirements, which apply to large and small quantity generators of hazardous waste and Toxic Release Inventory reporters. • State cleanup and remedial actions for hazardous substances, and separate rules for dry cleaning facilities with perchloroethylene (tetrachloroethylene). In addition, legacy contamination from industrial sites is still a potential source of exposure to several of the Initial Ten TSCA Chemicals. The Oregon Health Authority's Environmental Health Assessment Program evaluates potential public health risks from contaminated sites across our state. In the last year alone, the program has been asked to evaluate public health risks from sites where environmental monitoring projects detected at least one of the Initial Ten TSCA Chemicals, including 1,4 dioxane, carbon tetrachloride, methylene chloride, tetrachloroethylene, and/or trichloroethylene. • Oregon adopted the Toxic Free Kids Act in 2015, requiring manufacturers of children's products to report the presence of specific chemicals of concern in products sold in Oregon. Several of the Initial Ten TSCA Chemicals are being reported in that program, including 1,4 dioxane, methylene chloride, tetrachloroethylene, and hexabromocyclododecane. Oregon relies on information from federal agencies to evaluate potential health risks of chemicals of concern for children, to identify new chemicals of concern to add to the reporting list, and to help address cumulative risks from these chemicals through other routes of exposure.
Distric of Columbia: The District of Columbia's Hazardous Waste Management Act includes provisions for toxic chemical source reporting and reduction. Businesses identified by the Standard Industrial Classification (SIC) as the largest generators or within the top 25% of all hazardous waste generators within the District, or that release a toxic chemical subject to regulation are required to file an annual Toxic Release Inventory (TRI) Form R for each TRI-listed chemical it manufactures, processes or otherwise uses in quantities above the threshold reporting quantity. In addition, reporting facilities must prepare and submit a toxic chemical source reduction plan which must be updated every four years. TRI-listed chemicals include the following toxic substances included in the Initial Ten TSCA Chemicals: trichloroethylene, 1-bromopropane and n-methylpyrrolidone.

10	UCSF_CommentJune252030	2	Exposure, RegNex, Policy
11	UCSF_CommentJune252036	2	PESS
12	ACOEMCommentAugust82018	1	Exposure, PESS

2.2
2.3.5
2.3.5

Finally, in the exposure assessments for methylene chloride [p. 30 of Scope], N-methylpyrrolidone [pp. 19-20 of Scope] and trichloroethylene [p. 27 of Scope], EPA is proposing to exclude uses it already assessed. We agree that EPA does not need to re-assess these uses; these evaluations have been completed and finalized. However, unless and until such uses are banned, the exposures from these uses continue. Therefore, the new risk evaluations need to consider the contributions of these uses to exposures by using the exposure values from the previous assessments.
For example, the prenatal lifestage is the most sensitive to developmental and reproductive toxicants, and women of child-bearing age should be considered as a susceptible sub-population for any chemicals with such hazards. Women of reproductive age are not specifically identified as a potential susceptible sub-population for pigment violet 29, TCE, NMP, PERC, or HBCD, even though EPA will consider reproductive and developmental toxicity hazards for these chemicals.
We recognize that the literature on the health effects of exposure to trichloroethylene (TCE) is extensive. Additionally, ACOEM recognizes that occupationally exposed workers represent a particular susceptible subpopulation, deserving of special scrutiny.

13	ACOEMCommentAugust82018	1	RegNex, Human Health, Exposure
14	ACOEMCommentAugust82018	1	Fate
15	ACOEMCommentAugust82018	1	Exposure
16	ACOEMCommentAugust82018	1	Human Health, Exposure

N/A
2.3, 2.6.1
2.3.5, 2.6.1
2.3.5, 2.6.1

OSHA's current permissible exposure limit (PEL) for TCE (100 ppm for Federal OSHA, or 537 mg/cu m, as an 8-hour time-weighted average), would theoretically permit a worker to be exposed to as much as 2,500 mg of trichloroethylene per day, assuming a breathing rate of 10 cu meters per 8-hour shift and an absorption factor exceeding 50%. Exposures in this range over a lifetime would impose an incremental lifetime cancer risk for exposed workers markedly exceeding 1 chance in 100, taking account of the current cancer potency estimates for TCE. Such exposures are also strongly suspected to be associated with an increased risk for reproductive toxicity. ACOEM applauds EPA's previous recognition of these increased reproductive risks particularly in occupationally exposed populations. OSHA's current permissible exposure limit (PEL) for TCE (100 ppm for Federal OSHA, or 537 mg/cu m, as an 8-hour time-weighted average), would theoretically permit a worker to be exposed to as much as 2,500 mg of trichloroethylene per day, assuming a breathing rate of 10 cu meters per 8-hour shift and an absorption factor exceeding 50%. Exposures in this range over a lifetime would impose an incremental lifetime cancer risk for exposed workers markedly exceeding 1 chance in 100, taking account of the current cancer potency estimates for TCE. Such exposures are also strongly suspected to be associated with an increased risk for reproductive toxicity. ACOEM applauds EPA's previous recognition of these increased reproductive risks particularly in occupationally exposed populations.

In addition, ACOEM is concerned about the fate of TCE released into the environment, whether in the form of surface-run off, release from storage tanks, or other unintended releases. The extent of persistent groundwater contamination with TCE has been documented in many parts of the nation.

We urge EPA to consider all sources of exposure to trichloroethylene in potentially exposed workers, to assure that cumulative exposures from occupational uses, from ambient air, and/or from drinking water do not exceed an acceptable level.

Accordingly, ACOEM urges EPA to consider both the cancer and non-cancer health effects resulting from exposure to TCE, particularly in occupationally exposed populations, where exposure is likely to be highest.

17	ACOEMCommentAugust82018	1	Fate
18	ACOEMCommentAugust82018	1	General
19	HSIACommentJune62018	1	General
20	HSIACommentJune62018	1	Human Health
21	HSIACommentJune62018	1	Human Health

2.3., 2.6.1
N/A
N/A
N/A
N/A

Furthermore, given the long record of TCE environmental contamination, particularly involving groundwater, ACOEM encourages EPA to include in its chemical evaluation the environmental fate and environmental impacts of TCE use, both from intended uses, as well as from uses that may be unintended but are reasonably foreseeable.
Furthermore, ACOEM would see great merit in sharply restricting the use of TCE for degreasing operations.
The Halogenated Solvents Industry Alliance, Inc. (HSIA) is pleased to have the opportunity to offer these comments on EPA's proposed rule to strengthen transparency in regulatory science. 83 Fed. Reg. 18768 (April 30, 2018). The intent of this rule is to ensure that EPA uses scientific information in its assessments that is publicly available to allow for independent validation, particularly when the scientific studies are pivotal to regulatory action. HSIA represents producers and users of trichloroethylene (TCE), and HSIA's experience with assessments ofthat chemical by two EPA program offices has highlighted the need for greater transparency in that process.
In 2011 , EPA derived a reference concentration (RfC) of 0.0004 ppm (0.4 ppb or 2)ug/m3) and a reference dose (RfD) of 0.0005 mg/kg-day for TCE. EPA's derivation of the RfC/RfD for TCE was based, in part, on Johnson et al., Threshold of Trichloroethylene Contamination in Maternal Drinking Waters Affecting Fetal Heart Development in the Rat, Environ. Health Perspect. 111: 289-92 (2003). This assessment was subsequently adopted in the TSCA Chemicals Work Plan Assessment for TCE.
As noted in the proposed rule, both transparency and independent validation of key findings of a study (reproducibility) are necessary in EPA's scientific assessments to ensure "that the quality of published infonnation meets the standards of the scientific and technical community." For reasons discussed below, the Johnson et al. (2003) study meets neither of these standards and should not be used to develop toxicological values that serve as the basis for regulation.

22	HSIACommentJune62018	1	Other/Human Health
23	HSIACommentJune62018	1	Human Health

N/A
N/A

1. Data records for Johnson et al. (2003) are inadequate or non-existent

HSIA's attempts to see the raw data which formed the basis of the Johnson et al. (2003) study report have been unsuccessful. When HSIA requested access to the data used by EPA in its evaluation of the dose-response relationship between TCE exposure and cardiac defects reported in Johnson et al. (2003), the Agency provided the spreadsheet, referenced as Johnson (2009) (HERO ID 783484) in the 2011 IRIS Assessment, and indicated that was the entirety of the data evaluated. Examination of that spreadsheet reveals an absence of certain critical information, including most importantly dates for any of the individual treatment/control animals. Acknowledging the documented deficiencies in their paper (and the data provided to EPA), the authors published an erratum aimed at updating the public record regarding methodological issues for Johnson et al. (2003).

According to Makris et al. (2016): "some study reporting and methodological details remain unknown, e.g., the precise dates that each individual control animal was on study, maternal body weight/food consumption and clinical observation data, and the detailed results of analytical chemistry testing for dose concentration. Additional possible sources of uncertainty identified for these studies include that the research was conducted over a 6-year period, that combined control data were used for comparison to treated groups, and that exposure characterization may be imprecise because tap (rather than distilled) drinking water was used in the Dawson et al. (1993) study and because TCE intake values were derived from water consumption measures of group-housed animals."

HSIA submits that the information contained in the above paragraph alone constitutes a transparency as well as a data quality concern sufficient to preclude Johnson et al. (2003) from being used as the basis for regulation. A direct appeal to Dr. Johnson failed to make the data available for public scrutiny. And a Freedom of Information Act request pursuant to the Shelby Amendment was denied by the National Institutes of Health.

24	HSIACommentJune62018	1	Human Health

N/A

The transparency problem with Johnson et al. (2003) was pointed out by the peer review of the TSCA Chemicals Work Plan assessment for TCE. An excerpt from the peer review report is reproduced below: "Unfortunately, Johnson et al (2003) failed to report the source or age of their animals, their husbandry or provide comprehensive historical control data for spontaneous cardiovascular malformations in their colony. The Johnson study with 55 control litters compared to 4 affected litters of 9 treated was apparently conducted over a prolonged period of time (perhaps years); it is possible this was due to the time required to dissect and inspect fresh rodent fetuses by a small academic group. However, rodent background rates for malformations, anomalies and variants show temporal fluctuations (WHO, 1984) and it is not clear whether the changes reported by Johnson et al. (2005) were due to those fluctuations or to other factors. Surveys of spontaneous rates of terata in rats and other laboratory animals are common particularly in pharmaceutical and contract laboratory safety assessments (e.g., Fritz et al., 1978; Grauwiler, 1969; Palmer, 1972; Perraud, 1976). The World Health Organization (1984) advised: "'Control values should be collected and permanently recorded. They provide qualitative assurance of the nature of spontaneous malformations that occur in control populations. Such records also monitor the ability of the investigator to detect various subtle structural changes that occur in a variety of organ systems.' "Rates of spontaneous congenital defects in rodents can vary with temperature and housing conditions. For example, depending on the laboratory levocardia and cardiac hypertrophy occur in rats at background rates between 0.8-1.25% (Perraud, 1976). Laboratory conditions can also influence study outcome; for instance, maternal hyperthermia (as a result of ambient elevated temperature or infection) can induce congenital defects (including cardiovascular malformations) in rodents and it acts synergistically with other agents (Aoyama et al., 2002; Edwards, 1986; Zinskin and Morrissey, 2011). Thus while the anatomical observations made by Johnson et al. (2003) may be accurate, in the absence of data on maternal well-being (including body weight gain), study details (including investigator blind investigations), laboratory conditions, positive controls and historical rates of cardiac terata in the colony it is not possible to discern the differences between the Johnson et al. (2003) results and those of other groups. As noted by previous investigators, the rat fetus is 'clearly at risk both to parent TCE and its TCE metabolite' given sufficiently high prenatal TCE exposures that can induce neurobehavioral deficits (Fisher et al, 1999; Taylor et al., 1985), but no focus on cardicac terata limited to studies in one laboratory that have not been reproduced in other (higher dose) studies and apply the BMD01 with additional default toxicodynamic uncertainty factors appears misleading."

25	HSIACommentJune62018	1	Human Health
26	HSIACommentJune62018	1	Human Health

N/A
N/A

HSIA had consistently maintained that the data presented in Johnson et al. (2003) and subsequently clarified in the two errata do not allow calculations of the incidence of cardiac malformations per litter that is time-matched to concurrent controls (the standard practice for evaluation of developmental toxicity studies). Accepting the authors' claim in the 2014 erratum that exposure times cannot be confirmed for substantial amounts of either control or treatment data, it also can be presumed that it is now impossible to reconstruct a calculation of per litter incidence of cardiac malformations that is appropriately matched to concurrent controls. Thus, the data reported in Johnson et al. (2003), even as amended in two subsequent errata, do not allow for data analysis generally accepted as essential to interpreting outcomes of developmental toxicity study findings. The lack of data availability and clarity sufficient to construct key analyses associated with a key study should disqualify the use of that study in important decisions such as RfC/RfD derivations used for regulatory purposes.
2. Johnson et al. (2003) is not reproducible At least two GLP-compliant studies (Carney et al. 2006; Fisher et al. 2001) conducted under both EPA and Organization for Economic Coordination and Development (OECD) guidelines have been unable to reproduce the effect seen by Johnson et al. (2003), despite the participation in one of the studies by Johnson herself. Significant to the proposed transparency rule, Carney et al. (2006) was conducted as part of a voluntary testing program between the HSIA and the Agency for Toxic Substances & Disease Registry (ATSDR). All stages of the testing, from development of the protocol to the final report, underwent extensive peer review by scientists from three separate governmental agencies (ASTDR, EPA, and the National Toxicology Program), as well as external experts. In addition, the protocol and study report (which includes the raw data) are available to the public. Carney et al. (2006) meets the highest standard of transparency that can be achieved for EPA's assessment needs.

27	HSIACommentJune62018	1	Human Health
28	HSIACommentJune62018	1	Human Health/Exposure

N/A
N/A

A third guideline study of TCE developmental toxicity is now being sponsored by HSIA, with results expected by September 2018. The study is designed with a focus on cardiac abnormalities and includes toxicokinetic measures to enable comparison with the earlier studies. It is intended to fill the remaining gap for a guideline study by the drinking water route, the same exposure route as Johnson et al. (2003). Keeping TCE in the drinking water solutions and achieving acceptable target concentrations of TCE in the drinking water has been challenging because of the high propensity of TCE to volatilize into the air. For this reason, the concentrations of TCE in the drinking water formulations will be sampled prior to transfer into the rat drinking water bottles at multiple times during the study, including time points that bracket the period of fetal heart development. The study will also include a determination on how much TCE is lost from the dosing solutions in the water bottles when placed in the animal cages over the course of a 24-hour exposure period. All data will be made publicly available in the study report.

In summary, we support EPA's proposed transparency rule and point to the use of Johnson et al. (2003) in EPA's derivation of toxicological values for TCE as an example of why the rule is needed. There has been a great deal of public concern regarding cardiac malformations from exposure to TCE in indoor air as a consequence of EPA's derivation of the IRIS RfC/RfD for TCE using the Johnson et al. (2003) study. In 2014, EPA Region 9 issued action levels of 8 ug/m3 (commercial and industrial) for an 8-hour workday and 2 ug/m3 (residential) for short-term exposures to TCE at Superfund sites under its jurisdiction. The short-term exposure limit of 2 ug/m3 is based on the IRIS RfC/RfD for TCE and was intended by Region 9 "to be protective of sensitive and vulnerable populations, especially women in the first trimester of pregnancy, because of the potential for cardiac malformations to the developing fetus."

29	HSIACommentJune62018	1	Human Health, Exposure
30	HSIACommentAugust22018	2	Human Health
31	OhioUnivCommentAugust82018	1	Exposure

N/A
N/A
N/A

Mitigation measures to achieve this short-term exposure limit include evacuation of residents or workers from buildings. Regions 9's short-term exposure limit is now being adopted by states to protect against the risk of cardiac malformations from TCE exposure in indoor air from contaminated sites, even though the more relevant route of exposure for this regulatory action by federal and state agencies is by inhalation of TCE vapor and not orally from drinking water. The only animal developmental study conducted on TCE by the inhalation route (Carney et al. 2006) showed no indication of developmental toxicity, including cardiac malformations.
The Halogenated Solvents Industry Alliance, Inc. (HSIA) represents producers and users of trichloroethylene. We are submitting the protocol of the on-going HSIA-sponsored study titled "An Oral (Drinking Water) Study of the Effects of Trichloroethylene (TCE) on Fetal Heart Development in Sprague Dawley Rats." The purpose of this study is to replicate the findings of Johnson et al., Threshold of Trichloroethylene Contamination in Maternal Drinking Waters Affecting Fetal Heart Development in the Rat, Environ. Health Perspect. 111: 289-292 (2003).

[Letter addressed to Dr. Croyle of the National Cancer Institute (NCI)]
It was a pleasure to meet you in Washington, DC at the meeting of the State Leadership Council of the National Rural Health Association on July 18th. Thank you for coming to this meeting and for explaining NCI's emphasis on understanding cancers in rural areas.
As we briefly discussed, I have been working with colleagues to explore possible reasons for prostate cancer cases among men who were security guards at a uranium enrichment facility in rural, Appalachia Ohio. These men were diagnosed prior to the age of 60 with aggressive prostate cancer and it seems as if this is more common than expected. The information below summarizes the situation and includes a background of the facility for orientation purposes. I also include a synopsis of some of the work we have done, potential research questions and activities, and a request for support from NCI.

32	OhioUnivCommentAugust82018	1	Exposure
33	OhioUnivCommentAugust82018	1	Exposure

N/A
N/A

[Detailed descriptions of the following were provided: Background of the Portsmouth Gaseous Diffusion Plant ("PORTS"; a uranium enrichment plant in Ohio built in the 1950s), the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), background of former workers (specifically security guards), the relationship between prostate cancer and TCE exposure, and a pilot project conducted by ARHI.] [Pilot Project:] Faculty in the Appalachian Rural Health Institute (ARHI), the Environmental Health Science program, and the Department of Geography have been exploring the cases of prostate cancer at PORT. This pilot research has included: 1. Interviews and a focus group with former employees; 2. A class case-study project, involving former workers and U.S. EPA; and 3. Interviews with men who did not work at the plant. [description of interview and focus groups]
Class Project: Seniors at Ohio University in an Environmental Health and Safety Risk Assessment class conducted a case study of TCE. They ultimately made recommendations about whether it was "as least as likely as not" that there is a relationship between TCE and prostate cancer. As part of the case study, students heard presentations from former security guards and spoke with the U.S. EPA contact for the current risk evaluation for TCE. The risk evaluation was initiated in December of 2016 and the scope of the risk evaluation was published in June of 2017. The consensus of the students in this class was that there is a reason to further evaluate the relationship between TCE exposure and prostate cancer.

34	OhioUnivCommentAugust82018	1	Human Health
35	OhioUnivCommentAugust82018	1	Human Health

2.4
2.4

On June 11, 2018, US EPA opened a public comment period on the Problem Formulation of the Risk Evaluation for Trichloroethylene. On July 24, 2018, the public comment period was extended until August 16, 2018. Although the problem formulation document is not final, it does state that EPA expects that inhalation is likely to be the most important exposure pathway for workers who did not directly work with TCE. Health effects from direct inhalation exposure to TCE include throat irritation and heart arrhythmias. Health effects from inhalation episodes can be compounded in areas with high temperatures. This is because phosgene can form when chlorinated hydrocarbons (TCE included) are exposed to high temperatures. Phosgene is a poisonous gas and health effects from acute exposure include coughing, burning sensation in the throat and eyes, difficulty breathing, and nausea and vomiting. Like TCE, phosgene has been found all over the PORTS site and the SEM notes one documented incident of trichloroethylene and phosgene exposure in 1980 at PORTS.
[description of interviews] Although we are still analyzing the interview data, we have identified the following: 1) All the former PORTS security guards we interviewed (cases and controls) experienced at least one acute chemical exposure when responding to an incident at the site. 2) All the men we interviewed, except for control #4, believed they had been exposed to dangerous chemicals in their workplaces. 3) All the former PORTS security guards we interviewed, regardless of tenure and health status, believed that they were exposed to chemicals and radiation and these exposures were preventable if they had been provided with PPE. 4) None of the former plant workers had any knowledge of being exposed to TCE. However, the men who are being compensated for bilateral sensorineural hearing loss fall under Part E specifically from exposure to TCE.

26	OhioUnivCommentAugust82018	1	Exposure
37	OhioUnivCommentAugust82018	1	Exposure

N/A
N/A

Request for Support and Research Question. For almost two years we have been exploring the unusual cases of aggressive prostate cancer diagnosed in former security guards from PORTS at younger age than expected. During this work we have spoken to former workers at the plant, examined published research, talked with health officials, involved students, and interviewed men who did not work at the plant. We started this exploration looking for a possible connection between prostate cancer and radiation exposure, but this research question has evolved to address a possible association between TCE exposure and prostate cancer. A summary of our findings:

1) Some former security guards at PORTS have been diagnosed with aggressive prostate cancer at an earlier age than expected.
2) Some of the former security guards at PORTS who have been diagnosed with prostate cancer are currently receiving compensation for BSHL under Part E because of exposure to TCE.
3) Clean-up activities have identified TCE as one of the most common contaminants in groundwater at the site.
4) The site exposure matrix for PORTS identifies more than 80 chemicals that security guards could have been exposed to including TCE and phosgene.
5) Some previous research suggests an association between TCE and prostate cancer, but more research is needed.

These preliminary findings lead us to the overarching research question: Is there an association between exposure to TCE and prostate cancer?

To answer this question, we are requesting that NCI consider supporting a large case-control epidemiologic study that will greatly expand the work we have done in this pilot. The case definition would need to be expanded and refined. We would gather qualitative data through interviews and quantitative data through surveys. While there are limitations to this type of observational epidemiology, it could contribute to additional understanding about the likelihood of developing prostate cancer from environmental and occupational exposures. Furthermore, this case clearly addresses NCI's emphasis on understanding cancer in rural areas.

38	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	General
39	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	RegNex
40	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	General

N/A
N/A
N/A

The Halogenated Solvents Industry Alliance, Inc. (HSIA) represents producers and users of trichloroethylene. We offer these comments on EPA's problem formulation for the risk evaluation of trichloroethylene under the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act enacted in June 2016. 83 Fed. Reg. 26998 (June 11, 2018). HSIA agrees with the condition of use proposed in the problem formulation document as being appropriate for the risk evaluation and is pleased that EPA is implementing systematic review approaches in all aspects of the risk evaluation.
HSIA further agrees with EPA that legacy sources of exposure should be excluded from the risk evaluation of trichloroethylene. Legacy sources of exposure typically refer to historical releases of a chemical to the environment associated with misuse or disposal. Although legacy environmental sources of exposure certainly exist for trichloroethylene, they have been managed for decades under various federal programs (i.e., CERCLA, RCRA, CAA, etc.). Many states also have stringent programs for addressing legacy contamination from these chemicals. Management of legacy contamination through the various federal and state programs is already risk-based and adding an additional risk-management program to the existing mix would be duplicative and not needed
I. Requirements of TSCA §§ 6 and 26 TSCA § 6(b)(4)(F), as revised by the Lautenberg Act, requires that EPA's risk evaluations must, among other things: • "integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator;" • "take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance;" and • "describe the weight of the scientific evidence for the identified hazard and exposure."

41	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	General

N/A

New TSCA § 26(h) requires that, in carrying out § 6, "to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science, and shall consider as applicable—

(1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;

(2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;

(3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;

(4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and

(5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models."

Further, new TSCA § 26(i) provides: "The Administrator shall make decisions under sections 4, 5, and 6 based on the weight of the scientific evidence."

42	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Exposure
43	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health

2.2.2.2
N/A

The problem formulation for the risk evaluation of TCE includes degreasing and spot cleaning uses, which HSIA strongly supports. These two uses had been evaluated in 2014 in EPA's TSCA Work Plan Assessment for TCE, but the evaluation procedure was deficient as it did not comply with the "best available science" and "weight of scientific evidence" requirements under TSCA §§ 6 and 26. As the Chair noted in the peer review of the draft TSCA Work Plan Assessment: "The principal criterion for inclusion/exclusion [in the Work Plan assessment] would be the credibility/integrity of the study rather than simply the route of exposure. . . . If the Agency had conducted a systematic review of the literature and each study as it was developing the IRIS document, it would be a relatively easy task to identify the one best data set to represent the endpoint/duration of exposure /(sub)population to be evaluated. But there is not documentation to show that this exercise was carried out. . . . If [OPPT] didn't do its own systematic review of those . . . studies before using them, in the screening level assessment, it should do it before keeping them in a refined assessment."
II Non-Cancer Assessment. A. Re-assessment of cardiac malformations from Johnson et al (2003) study. EPA's derivation of the current inhalation reference concentration (RfC) and oral reference dose (RfD) for TCE in its IRIS database is based, in part, on Johnson et al., Threshold of Trichloroethylene Contamination in Maternal Drinking Waters Affecting Fetal Heart Development in the Rat, Environ. Health Perspect. 111: 289-92 (2003). At least two GLP-compliant studies (Carney et al. 2006; Fisher et al. 2001) conducted under both EPA and Organization for Economic Coordination and Development (OECD) guidelines have been unable to reproduce the effect seen by Johnson et al. (2003).

44	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health
45	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health, Fate

N/A
N/A

A third guideline study of TCE developmental toxicity sponsored by HSIA is underway, and the results are expected by the end of October 2018. The study is designed with a focus on cardiac abnormalities and includes toxicokinetic measures to enable comparison with the earlier studies. It is intended to fill the remaining gap for a guideline study by the drinking water route, the same exposure route as Johnson et al. (2003). Keeping TCE in the drinking water solutions and achieving acceptable target concentrations of TCE in the drinking water has been challenging because of the high propensity of TCE to volatilize into the air, as illustrated below in Table 1 [p. 4 of comments] Table 1 lists the vapor pressure, water solubility, and Henry's Law constant for TCE and several other volatile chemicals that have been tested in drinking water toxicity studies.
The Henry's Law constant is the equilibrium distribution of a chemical between the concentration in air and the concentration in water; it is commonly derived simply as the ratio of vapor pressure and solubility. A comparison of the Henry's Law constants for the volatile chemicals in Table 1 shows that TCE has a far greater tendency to transfer to air than the other volatile chemicals. While there were no reported problems of volatility loss of chloroform, EDC, MTBE, or acetone from the drinking water formulations in animal toxicity studies, this was found to be problematic in the earlier drinking water study sponsored at the same laboratory by HSIA. In this study, there was a significant problem with TCE volatility loss during the preparation of the dosing formulations and in the transfer of these formulations to the drinking water bottles; it was particularly severe at the lower concentrations (0.25 and 1.5 ppm TCE). Johnson et al. (2003) reported a 34% loss of TCE from the drinking water bottles over the 24-hour period in the animal cages, but the laboratory provided almost no information on the method used to minimize TCE loss during the preparation step of the dosing formulations, the concentrations of TCE achieved in the drinking water bottles at the start of each exposure period, and the variability of these concentrations throughout the study. This lack of reporting detail and analytical chemistry testing data for dose concentrations has been identified as one of the many deficiencies of the Johnson et al. (2003) study (Makris et al., 2016; Wikoff et al., 2018).

46	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health, Fate

N/A

For the re-run of the HSIA-sponsored TCE developmental toxicity study, a method has been developed by the testing facility that allows the target concentrations to be met within a reasonable range. The method involves preparing the dosing formulations on a daily basis and in a closed system; headspace is minimized. For the transfer of the dosing formulations into the water bottles, nitrogen is pumped into the inlet valve of the dosing formulation vessel, displacing the dosing formulation through the outlet value and into the drinking water bottle. A feasibility study was recently conducted to ensure that the dosing formulations could be prepared consistently on a daily basis and to quantitate how much TCE loss would occur from the drinking water bottles over the 24-hour period in the animal cages. Pregnant female SD Crl:CD(SD) rats were given in their drinking water 0.25 or 1,000 ppm TCE from gestation days (GD) 11 to 13. The dosing formulations were given to the rats at the same time of the day (within 2-3 hours) on GD 11 and 12. For the 1,000 ppm TCE dose group, the concentrations of TCE in the prepared dosing formulations for the two test days were 97% and 105% of the target concentration, and 102% and 103% after being added to the water bottles. For the 0.25 ppm TCE dose group, the concentrations of TCE in the dosing formulations for the two days were 136% and 123% of the target concentrations, and 132% and 132% after being added to the water bottles. The losses of TCE from the water bottles over the 24-hour period were 34% and 31% for the 0.25 and 1,000 ppm dosing groups, respectively. While the TCE losses from the water bottles over the 24-hour exposure period are unavoidable, these results show that the method developed by the testing facility for the HSIA-sponsored developmental study achieves minimal TCE volatility loss, resulting in consistent daily TCE drinking water concentration.

47	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health
48	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health

N/A
N/A

B. Critiques of Johnson et al. (2003) in literature and by other regulators. Johnson et al. (2003) reported cardiac effects in rats from research carried out at the University of Arizona and originally published ten years earlier by the same authors.7 In the earlier-published study, there was no difference in the percentage of cardiac abnormalities in rats dosed during both pre-mating and pregnancy at drinking water exposures of 1100 ppm (9.2%) and 1.5 ppm (8.2%), even though there was a 733-fold difference in the concentrations. The authors reported that the effects seen at these exposures were statistically higher than the percent abnormalities in controls (3%). For animals dosed only during the pregnancy period, the abnormalities in rats dosed at 1100 ppm (10.4%) were statistically higher than at 1.5 ppm (5.5%), but those dosed at 1.5 ppm were not statistically different from the controls. Thus, no meaningful dose-response relationship was observed in either treatment group. Johnson et al. republished in 2003 data from the 1.5 and 1100 ppm dose groups published by Dawson et al. in 1993 and pooled control data from other studies, an inappropriate statistical practice, to conclude that rats exposed to levels of TCE greater than 250 ppb during pregnancy have increased incidences of cardiac malformations in their fetuses.
Johnson et al. (2003) has been heavily criticized in the published literature. Indeed, its predecessor study was expressly rejected as the basis for MRLs by the Agency for Toxic Substances & Disease Registry (ATSDR) in its last TCE Toxicological Profile Update. Moreover, as noted above, the Johnson et al. (2003) findings were not reproduced in a study designed to detect cardiac malformations; this despite employing an improved method for assessing cardiac defects and the participation of Dr. Johnson herself. No increase in cardiac malformations was observed in the second guideline study, despite high inhalation doses and techniques capable of detecting most of the malformation types reported by Johnson et al. (2003). The dose-response relationship reported in Johnson et al. (2003) for doses spanning an extreme range of experimental dose levels is considered by many to be improbable, and has not been replicated by any other laboratory.

49	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health
50	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health

N/A
N/A

Even the California Office of Environmental Health Hazard Assessment (OEHHA) rejected the study as deficient: "Johnson et al. (2003) reported a dose-related increased incidence of abnormal hearts in offspring of Sprague Dawley rats treated during pregnancy with 0, 2.5 ppb, 250 ppb, 1.5 ppm, and 1,100 ppm TCE in drinking water (0, 0.00045, 0.048, 0.218, and 128.52 mg/kg-day, respectively). The NOAEL for the Johnson study was reported to be 2.5 ppb (0.00045 mg/kg-day) in this short exposure (22 days) study. The percentage of abnormal hearts in the control group was 2.2 percent, and in the treated groups was 0 percent (low dose), 4.5 percent (mid dose 1), 5.0 percent (mid dose 2), and 10.5 percent (high dose). The number of litters with fetuses with abnormal hearts was 16.4 percent, 0 percent, 44 percent, 38 percent, and 67 percent for the control, low, mid 1, mid 2, and high dose, respectively. The reported NOAEL is separated by 100-fold from the next higher dose level. The data for this study were not used to calculate a public-health protective concentration since a meaningful or interpretable dose-response relationship was not observed. These results are also not consistent with earlier developmental and reproductive toxicological studies done outside this lab in mice, rats, and rabbits: The other studies did not find adverse effects on fertility or embryonic development, aside from those associated with maternal toxicity (Hardin et al., 2004)."

C. Reservations by EPA scientific staff. Remarkably, an EPA staff review that was placed in the docket for the earlier Work Plan Assessment reflects similar concerns. First, one staff member dissented over relying at all on the Arizona study:

"The rodent developmental toxicology studies conducted by Dawson et al. (1993), Johnson et al. (2003), and Johnson et al. (1998) that have reported cardiac defects resulting from TCE (and metabolite) drinking water exposures have study design and reporting limitations. Additionally, two good quality (GLP) inhalation and gavage rodent studies conducted in other laboratories, Carney et al. (2006) and Fisher et al. (2001), respectively, have not detected cardiac defects. These limitations and uncertainties were the basis of the single dissenting opinion of a team member regarding whether the database supports a conclusion that TCE exposures during development are likely to cause cardiac defects."

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N/A
N/A

Second, even the EPA staff that agreed with use of the study had little confidence that it supported the dose-response assessment: "[A] majority of the team members agreed that the Johnson et al. (2003) study was suitable for use in deriving a point of departure. However, confidence of team members in the dose response evaluation of the cardiac defect data from the Johnson et al. (2003) study was characterized as between 'low' and 'medium' (with 7 of 11 team members rating confidence as 'low' and four team members rating confidence as 'low to medium'). The same report notes: "In conclusion, there has not been a confirmation of the results of the Johnson et al. (2003) and Dawson et al. (1993) studies by another laboratory, but there has also not been a repeat of the exact same study design that would corroborate or refute their findings."
D. EPA's dose-response analysis of Johnson et al. (2003) data needs to be re-examined. The IRIS assessment's evaluation of the relationship between TCE exposure dose and the development of cardiac defects relies heavily on Johnson et al. (2003). Ignoring for the moment the methodological deficiencies in the paper, a closer look at EPA's evaluation of that dose-response relationship in generating a point of departure (POD) raises several concerns. This is important, as according to a paper published by the authors of the IRIS Assessment, Johnson et al. (2003) represents "the only available study potentially useable for dose-response analysis of fetal cardiac defects."

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N/A
N/A

In discussing the dose-response evaluation, Makris et al. (2016) further state that "[g]iven the uncertainties in the dose-response analysis related to the nature of the data, the confidence in the POD based on Johnson et al. (2003) has limitations. Overall, however, the POD derived in the 2011 TCE assessment (U.S. EPA, 2011), which used an approach consistent with standard U.S. EPA dose-response practices, remains a reasonable choice." It should be noted that, in order to achieve a better model fit in its derivation of a POD, EPA dropped the highest exposure dose from Johnson et al. (2003). With already questionable data, and no expectation that the highest dose of TCE would result in a diminished response, that decision should be reconsidered. Makris et al. (2016) describe additional dose-response analyses performed to characterize the uncertainty in the POD. In summarizing the results of this analysis, they state that "[a]lternative PODs were derived based on use of alternative models, alternative BMR levels, or alternative procedures (such as LOAEL/NOAEL approach), each with different strengths and limitations. These alternatives were within about an order of magnitude of the POD derived in the 2011 TCE assessment" (emphasis added). This level of uncertainty in modeling the POD when combined with the uncertainty in the PBPK modeling (discussed elsewhere) and the overall poor quality of the underlying developmental toxicity study provide little confidence in this toxicological value.
E. Reliance of Johnson et al. (2003) is inconsistent with use of best available science. When HSIA requested access to the data used by EPA in its evaluation of the dose-response relationship between TCE exposure and cardiac defects reported in Johnson et al. (2003), the Agency provided the spreadsheet, referenced as Johnson (2009) (HERO ID 783484) in the 2011 IRIS Assessment, and indicated that was the entirety of the data evaluated. Examination of that spreadsheet reveals an absence of certain critical information, including, most importantly, dates for any of the individual treatment/control animals.

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N/A
N/A
N/A

Acknowledging the documented deficiencies in their paper (and the data provided to EPA), the authors published an erratum aimed at updating the public record regarding methodological issues for Johnson et al. (2003). According to Makris et al. (2016): "some study reporting and methodological details remain unknown, e.g., the precise dates that each individual control animal was on study, maternal body weight/food consumption and clinical observation data, and the detailed results of analytical chemistry testing for dose concentration. Additional possible sources of uncertainty identified for these studies include that the research was conducted over a 6-yr period, that combined control data were used for comparison to treated groups, and that exposure characterization may be imprecise because tap (rather than distilled) drinking water was used in the Dawson et al. (1993) study and because TCE intake values were derived from water consumption measures of group-housed animals." HSIA submits that the information contained in the above paragraph alone should disqualify Johnson et al. (2003) as "best available science" as required under EPA's July 2017 procedures for chemical risk evaluation under TSCA as amended.
III. Cancer Risk Assessment. A. Deficiencies of Cancer Risk Assessment. 1. Erroneous Characterization of TCE as "Carcinogenic to Humans": The IRIS Assessment classifies TCE as "Carcinogenic to Humans." It fails to discuss (or even to recognize) that such classification is inconsistent with a definitive report by the National Academy of Sciences, discussed below. First, we briefly address how the epidemiological data on TCE do not meet the threshold for classification as "Carcinogenic to Humans."
a. Guidelines for Carcinogen Risk Asessment. EPA's 2005 Guidelines for Carcinogen Risk Assessment provide the following descriptors as to the weight of evidence for carcinogenicity: • Carcinogenic to humans, • Likely to be carcinogenic to humans, • Suggestive evidence of carcinogenicity, • Inadequate information to assess carcinogenic potential, and • Not likely to be carcinogenic to humans.

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N/A

According to the Guidelines, “carcinogenic to humans” means the following: “This descriptor indicates strong evidence of human carcinogenicity. It covers different combinations of evidence.

• “This descriptor is appropriate when there is convincing epidemiologic evidence of a causal association between human exposure and cancer.

•“Exceptionally, this descriptor may be equally appropriate with a lesser weight of epidemiologic evidence that is strengthened by other lines of evidence. It can be used when all of the following conditions are met: (a) There is strong evidence of an association between human exposure and either cancer or the key precursor events of the agent's mode of action but not enough for a causal association, and (b) there is extensive evidence of carcinogenicity in animals, and (c) the mode(s) of carcinogenic action and associated key precursor events have been identified in animals, and (d) there is strong evidence that the key precursor events that precede the cancer response in animals are anticipated to occur in humans and progress to tumors, based on available biological information. In this case, the narrative includes a summary of both the experimental and epidemiologic information on mode of action and also an indication of the relative weight that each source of information carries, e.g., based on human information, based on limited human and extensive animal experiments.”

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N/A

According to the Guidelines, the descriptor "likely to be carcinogenic to humans": "is appropriate when the weight of the evidence is adequate to demonstrate carcinogenic potential to humans but does not reach the weight of evidence for the descriptor 'Carcinogenic to Humans.' Adequate evidence consistent with this descriptor covers a broad spectrum. . . . Supporting data for this descriptor may include:

- "An agent demonstrating a plausible (but not definitively causal) association between human exposure and cancer;
- "An agent that has tested positive in animal experiments in more than one species, sex, strain, site or exposure route, with or without evidence of carcinogenicity in humans;
- "A positive tumor study that raises additional biological concerns beyond that of a statistically significant result, for example, a high degree of malignancy or an early age at onset;
- "A rare animal tumor response in a single experiment that is assumed to be relevant to humans; or
- "A positive tumor study that is strengthened by other lines of evidence."

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N/A

According to the Guidelines, the descriptor “suggestive evidence of carcinogenicity”: “is appropriate when the weight of evidence is suggestive of carcinogenicity; a concern for potential carcinogenic effects in humans is raised, but the data are judged not sufficient for a stronger conclusion. This descriptor covers a spectrum of evidence associated with varying levels of concern for carcinogenicity, ranging from a positive cancer result in the only study on an agent to a single positive cancer result in an extensive database that includes negative studies in other species. Depending on the extent of the database, additional studies may or may not provide further insights. Some examples include:

- “A small, and possibly not statistically significant, increase in tumor incidence observed in a single animal or human study that does not reach the weight of evidence for the descriptor ‘Likely to Be Carcinogenic to Humans;’
- “A small increase in a tumor with a high background rate in that sex and strain, when there is some but insufficient evidence that the observed tumors may be due to intrinsic factors that cause background tumors and not due to the agent being assessed;
- “Evidence of a positive response in a study whose power, design, or conduct limits the ability to draw a confident conclusion (but does not make the study fatally flawed), but where the carcinogenic potential is strengthened by other lines of evidence; or
- “A statistically significant increase at one dose only, but no significant response at the other doses and no overall trend.”

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N/A

b. Application of the Guidelines to TCE. In considering the data in the context of applying the "Carcinogenic to Humans" descriptor, the weight of the epidemiological evidence must first be considered. We judge the epidemiologic evidence to be neither "convincing" nor "strong," two key terms in the Guidelines. This judgment is based on four recent reviews and meta-analyses of occupational TCE exposures and cancer as well as other reviews of this literature.20 The recent review and meta-analysis by Kelsh et al. focuses on occupational TCE exposure and kidney cancer, and includes the Charbotel et al. study that is emphasized in the IRIS assessment.21 Both the EPA meta-analysis and the Kelsh et al. meta-analysis of the TCE kidney cancer epidemiologic literature produced similar summary results. However in Kelsh et al. the limitations of this body of research, namely exposure assessment limitations, potential unmeasured confounding, potential selection biases, and inconsistent findings across groups of studies, did not allow for a conclusion that there is sufficient evidence of a causal association, despite a modest overall association.

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N/A

There are reasonably well-designed and well-conducted epidemiologic studies that report no association between TCE and cancer, some reasonably well-designed and conducted studies that did report associations between TCE and cancer, and finally some relatively poorly designed studies reporting both positive and negative findings. Overall, the summary relative risks or odds ratios in the meta-analysis studies (EPA or published meta-analyses) generally ranged between 1.2 and 1.4. Such small odds ratios are not typically considered “convincing” or “strong.” Weak or small associations may be more likely to be influenced by or be the result of confounding or bias. Smoking and body mass index are well-established risk factors for kidney cancer, and smoking and alcohol are risk factors for liver cancer, yet the potential impact of these factors on the meta-analysis associations was not fully considered. There were suggestions that these factors may have impacted findings (e.g., in the large Danish cohort study of TCE exposed workers, the researchers noted that smoking was more prevalent among the TCE exposed populations, however little empirical data were provided). In addition, co-linearity of occupational exposures (i.e., TCE exposure correlated with chemical and/or other exposures) may make it difficult to isolate potential effects of TCE from those of other exposures within a given study, and hinder interpretation across studies. For example, although Charbotel et al. reported potential exposure response trends, while controlling for many confounders of concern (which strengthens the weight of evidence), they also reported attenuated associations for cumulative TCE exposure after adjustment for exposure to cutting fluids and other petroleum oils (weakening the weight of the evidence). This study is also limited due to other potential study design considerations such as selection bias, self reporting of work histories, and residual confounding.

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N/A
N/A

When examining the data for TCE and non-Hodgkin lymphoma, kidney cancer, and liver cancer, associations were inconsistent across occupational groups (summary results differed between aerospace/aircraft worker cohorts compared with workers from other industries), study design, location of the study, quality of exposure assessment (e.g., evaluating studies that relied upon biomonitoring to estimate exposure vs. semi-quantitative estimates vs. self-report, etc.), and by incidence vs. mortality endpoints. Although EPA examined high dose categories, it did not evaluate any potential dose-response relationships across the epidemiologic studies (except for Charbotel et al.). Reviews of the epidemiologic data reported in various studies for different exposure levels (e.g., cumulative exposure and duration of exposure metrics) did not find consistent dose-response associations between TCE and the three cancer sites under review. An established dose-response trend is one of the more important factors when making assessments of causation in epidemiologic literature. Thus, based on an overall weight of evidence analysis of the epidemiologic research, these data do not support the conclusion that there is "strong" or "convincing" evidence of a causal association between human exposure and cancer.
EPA's Guidelines also state that a chemical may be described as "Carcinogenic to Humans" with a lesser weight of epidemiologic evidence that is strengthened by other lines of evidence, all of which must be met. One of these lines of evidence is "extensive evidence of carcinogenicity in animals." Therefore, we must briefly evaluate the animal data. The criteria that have to be met for animal data to support a "carcinogenic to humans" classification are stated in a sequential manner with an emphasized requirement that all criteria have to be met. Since the Guidelines consider this to be an "exceptional" route to a "carcinogenic to humans" classification, we would expect rigor to have been applied in assessing animal data against the criteria. This simply was not done.

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N/A
2.4.2.2

Of the four primary tissues that EPA evaluated for carcinogenicity, only one or perhaps two rise to the level of biological significance. Discussion of the remaining tumor types appears to presuppose that TCE is carcinogenic. The resulting discussion appears then to overly discount negative data, of which there are many, and to highlight marginal findings. The text does not appear to be a dispassionate rendering of the available data. Specifically, EPA's conclusion that kidney cancer is evident in rats rests on one statistically significant finding in over 70 dose/tumor endpoint comparisons and references to exceedances of historical control values.23 Using a 0.05 p-value for statistical significance, a frequency of 1 or even several statistically or biologically significant events is expected in such a large number of dosed/tumor groups. EPA's overall conclusion based on these flawed studies cannot be that TCE is a known kidney tumorigen. The best that can be said is that the data are inconsistent. Certainly they do not meet the criterion of "extensive evidence of carcinogenicity in animals." Several marginal findings do not constitute "extensive evidence." For all these reasons, EPA's classification of TCE as "Carcinogenic to Humans" is not supported by the evidence and cannot be justified under the 2005 Guidelines.

Footnote:

23 And that bioassay is from a laboratory whose studies EPA has reviewed and declined to rely upon in other assessments.

c. EPA's Position that there is 'Convincing Evidence' that TCE Is Carcinogenic to Humans is Inconsistent with National Academy of Sciences Conclusion of only 'Limited or Suggestive Evidence' The IRIS Assessment states that "TCE is characterized as 'carcinogenic to humans' by all routes of exposure. This conclusion is based on convincing evidence of a causal association between TCE exposure in humans and kidney cancer."

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2.4.2.2
2.4.2.2
2.4.2.2

Box 2 of the Academy's Camp Lejeune report, attached as Appendix 1, categorizes every cancer outcome reviewed in relation to exposure to TCE, the dry cleaning solvent perchloroethylene, or a mixture of the two. The categories are taken directly from a respected Institute of Medicine (IOM) report. These categories are "sufficient evidence of a causal relationship," "sufficient evidence of an association," "limited or suggestive evidence of an association," "inadequate evidence to determine an association," and "limited or suggestive evidence of no association," all as defined in Box 1, also attached. Looking at Box 2, evidence considered by EPA to be "convincing evidence of a causal association between TCE exposure in humans and kidney cancer" would seem to be considered "sufficient evidence of a causal relationship." Yet the Academy found no outcomes in that category. It would at least be "sufficient evidence of an association." Again, the Academy found no outcomes in that category. Only in the third category, "limited or suggestive evidence of an association," does one find kidney or any other cancer outcome associated with TCE.
"Limited evidence of an association" is far from "convincing evidence of causation." One would expect at the least a detailed explanation of EPA's very different conclusion. Although the 2009 Camp Lejeune study was already published, and indeed is cited in the references, there is no mention of it in the text of the IRIS Assessment, even though the previous draft had just been the subject of a multi-year review by the Academy.
The Camp Lejeune committee began with a comprehensive review of the epidemiology studies of the two solvents by the IOM for its Gulf War Report. They then identified new studies published from 2003 to 2008 and considered whether these changed the conclusions in the IOM report. In the case of TCE and kidney cancer, this was the case. The Camp Lejeune committee considered six new cohort studies and two case-control studies (including Charbotel et al.). They concluded that several of these studies reported an increased risk of kidney cancer, but observed that the results were often based on a relatively small number of exposed persons and varied quality of exposure data and methodology. Given these data, the committee raised the classification for TCE to match the IOM conclusion of "limited" evidence for perchloroethylene.

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2.4.2.2
2.4.2.2
2.4.2.2

EPA, on the other hand, offered the summary conclusion of convincing human evidence, based on the "consistency" of increased kidney cancer across the different studies. The authors of these studies, however, do not agree with EPA's characterization of them. For example, the authors of Charbotel et al., the study EPA finds most compelling, state that the "study suggests an association between exposures to high levels of TCE and increased risk of [renal cell carcinoma]. Further epidemiological studies are necessary to analyze the effect of lower levels of exposure."
Given the flaws in the IRIS Assessment, and the very different conclusion reached by the Academy in its Camp Lejeune report on the same body of data, the forthcoming evaluation under TSCA as amended should not rely on the IRIS Assessment's classification of TCE as "Carcinogenic to Humans."
2. EPA Should Reassess Available Cancer Epidemiology Data, Given Publication of More Recent and Larger Studies on Worker Populations. The observation of an elevated but weak kidney cancer association reported by Charbotel et al. (2006) contrasts with other occupational studies which did not find an elevation in kidney cancer in industries using TCE as a metal degreaser, e.g., aircraft manufacturing, metal cleaning, etc., where exposures may be higher than for screw cutters. Lipworth and coworkers (2011) found no evidence of increased kidney cancer in a large worker cohort with multiple decades of TCE exposure and extended cancer follow-up evaluations. The aircraft manufacturing study involved a total cohort of 77,943 workers, of which 5,443 were identified as exposed to TCE. The study involved evaluations from 1960 through 2008, at which time 34,248 workers had died. Approximately 30% of the workers were hired before 1960 (60% born before 1940), 52% terminated employment by 1980, and approximately a third of the workers were employed for more than 20 years. The standardized incidence ratio (SIR) for kidney cancer in the TCE-exposed workers was reported as 0.66 (CI 95%: 0.38-1.07). This value for the SIR indicates that these workers were potentially less likely to get kidney cancer than the normal population (or at least had the same rate as the normal population – SIR of 1).

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2.4.2.2
2.4.2.2

More recently, two large Nordic country epidemiological studies, both of which had extensive follow-up of the cohorts, have likewise failed to find an association between TCE and kidney cancer. An SIR of 1.01 (0.70-1.42) was found by Hansen et al. (2013) for kidney cancer based on 32 cases out of a total of 997 cancer cases in a cohort of 5,553 workers in Finland, Sweden, and Denmark, indicating that rates were the same as the normal population. TCE exposures in this cohort were directly confirmed from urinary biomonitoring of the TCE metabolite trichloroacetic acid (TCA). However, overall TCE exposures were likely low in this cohort in that most urinary TCA measurements were less than 50 mg/L, corresponding to approximately 20 ppm TCE exposure. Thus, consistent with the conclusions of Bruning and Bolt (2000), this study indicates TCE is unlikely to be a low-dose kidney carcinogen.
Similarly, no evidence of kidney cancer was found by Vlaanderen et al. (2013) in a recent follow-up examination of the Nordic Occupational Cancer cohort (Finland, Iceland, Norway, Sweden) in which statistically non-significant risk ratios (RR) of 1.01 (0.95-1.07), 1.02 (0.97-1.08), and 1.00 (0.95-1.07) were reported for a total of 4,145 renal cancer cases approximately equally distributed across three respective TCE exposure groups (tertiles) assigned from a job exposure matrix analysis. Finally, although a meta-analysis of 23 studies meeting criteria for study inclusion found a slightly increased simple summary association of TCE and kidney cancer, RR 1.42 (1.17-1.77), more detailed analyses of subgroups suggested no association, or possibly a moderate elevation in kidney cancer risk, and no evidence of increasing risk with increasing exposure. These more recent studies were not reviewed in the 2011 TCE IRIS assessment.

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2.4.2.2
2.4.2.2

3. EPA's reliance on Charbotel et al. (2006) Resulted in an Overly Conservative Estimate of Risk. The inhalation unit risk (IUR) value developed in the 2011 IRIS assessment was based primarily on epidemiology data from the case-control study on renal cell carcinoma (RCC) by Charbotel et al. (2006), discussed above. Although other epidemiological studies were used to derive an adjusted IUR estimate for the combined risk of developing RCC, NHL, or liver cancer, EPA concedes a lower level of confidence in both the NHL and liver cancer databases. While the Charbotel et al. study suggests a relationship between cumulative TCE exposure and RCC incidence, the reliability of the exposure estimates is a major concern.
The National Academy of Sciences Committee that reviewed the draft IRIS assessment released in 2001 recommended that: "[t]here appear to be insufficient epidemiologic data to support quantitative dose-response modeling for trichloroethylene and cancer. The committee recommends that toxicologic data be used to fit the primary dose-response model(s) and that the available epidemiologic data be used only for validation. The committee does not believe that the available information is sufficient to determine the best dose-response model for trichloroethylene."

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2.4.2.2
2.4.2.2

EPA should follow the recommendation of the National Academy of Sciences, which referenced the Charbotel et al. (2005) final study report in its review of TCE. The authors' own conclusions that the study only "suggests that there is a weak association between exposures to TRI [TCE] and increased risk of RCC" argues against the existence of the robust relationship which should be required for a dose-response assessment that may be used as the basis for regulation.33 Footnote: 33 This concern was recognized by the European Chemicals Agency (ECHA) in its 2013 Chemical Safety Report on TCE: "[T]here are several concerns with this study that should be taken into consideration when assessing its use in risk assessment and hazard characterization. For example, potential selection bias, the quality of the exposure assessment, and the potential confounding due to other exposures in the work place. With respect to the potential for selection bias, no cancer registry was available for this region to identify all relevant renal cell cancer cases from the target population. Case ascertainment relied on records of local urologists and regional medical centers; therefore, selection bias may be a concern. Given the concerns of the medical community in this region regarding renal cell cancer (RCC) among screw cutting industry workers, it is likely that any cases of renal cell cancer among these workers would likely be diagnosed more accurately and earlier. It is also much more unlikely that an RCC case among these workers would be missed compared to the chance of missing an RCC case among other workers not exposed to TCE. This preference in identifying cases among screw-cutting industry workers would bias findings in an upward direction. Concerning the potential for other exposures that could have contributed to the association, screw-cutting industry workers used a variety of oils and other solvents. Charbotel et al. reported lower risks for TCE exposure and renal cell cancer once data were adjusted for cutting oils. In fact, they noted, 'Indeed many patients had been exposed to TCE in screw-cutting workshops, where cutting fluids are widely used, making it difficult to distinguish between cutting oil and TCE effects.' This uncertainty questions the reliability of using data from Charbotel et al. since one cannot be certain that the observed correlation between kidney cancer and exposure is due to trichloroethylene."
The exposure assessment for the Charbotel study was based on questionnaires and expert judgment, not direct measures of exposure. Worker exposure data from deceased individuals were included in the study. In contrast to living workers, who were able to respond to the questionnaires themselves, exposure information from deceased workers (22.1% of cases and 2.2% of controls) was provided by surviving family members. The authors acknowledge that "this may have led to a misclassification for exposure to TCE due to the lower levels in the quality of information collected."

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2.4.2.2
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2.4.2.2
2.4.2.2

Analysis of the data revealed evidence of confounding from cutting fluid exposure. Unfortunately, TCE and cutting oil were co-exposures that could not be disaggregated and the majority of the TCE exposed population, the screw cutters, could be expected to experience similar patterns of exposure for both TCE and cutting fluids (probably in aerosol form). Thus, the apparent dose-response relationship for TCE could be wholly, or in part, the result of exposure to cutting fluids.
In their 2006 publication of the study results, the authors assigned cumulative exposures into tertiles (i.e., low, medium and high), yet the dose-response evaluation conducted as part of the IRIS assessment relied on mean cumulative exposure levels provided at a later date. Although the IRIS assessment references the email submission of the data to EPA, it provides no detail on the technical basis for the table, raising serious transparency issues.
In an apparent acknowledgement of the uncertainty of the exposure information, Charbotel et al. (2006) included an evaluation of "the impact of including deceased patients (proxy interviews) and elderly patients (>80 years of age)" on the relationship between exposure to TCE and RCC. Interestingly, it was stated that "only job periods with a high level of confidence with respect to TCE exposure were considered" in the study, an apparent reference to the use of two different occupational questionnaires, one "devoted to the screw-cutting industry and a general one for other jobs." As the Adjusted Odds Ratio (OR) for the high cumulative dose group was actually higher in the censored subgroup than in the uncensored group [3.34 (1.27-8.74) vs 2.16 (1.02-4.60)], the authors suggested that "misclassification bias may have led to an underestimation of the risk."
What the authors and EPA appear to have overlooked is that, in addressing the misclassification bias, Charbotel may also have altered the cumulative dose-response relationship. For example, in the censored subgroup there were now only 16 exposed cases (1 in the Low Group, 4 in the Medium Group and 11 in the High Group) with Adjusted ORs of 0.85, 1.03 and 3.34, respectively. If the dose-response relationship in this higher-confidence subgroup has changed, use of the lower-confidence group to calculate the IUR would require rigorous justification.

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2.4.2.2
2.4.2.2

4. EPA's Adjustment of the Kidney Cancer-Based IUR Value for TCE to Account for Potential Liver Cancer and Non-Hodgkin's Lymphoma (NHL) Endpoints is Not Scientifically Defensible and Needs to be Reconsidered. In addition to our concerns about the appropriateness of basing the IUR for TCE on epidemiology data, as described above, HSIA has serious concerns about the scientific appropriateness of adjusting the IUR derived from kidney cancer data to account for non-Hodgkin's lymphoma (NHL) and liver cancer. Derivation of the modified IUR is described in Section 5.2.2.2 of the IRIS Assessment. A recent review sponsored by HSIA concludes that it was not appropriate for EPA to adjust the IUR based on kidney cancer for multiple cancer sites because the available epidemiology data are not sufficiently robust to allow such calculations and the data that are available indicate that the IUR for kidney cancer is protective for all three cancer types. See Appendix 2 (attached) for a complete discussion of this issue.
5. A Role for Glutathione Conjugate-derived Metabolites in TCE Kidney Toxicity and Cancer Risk Assessment Should be Reconsidered. The TCE IRIS Assessment relies in part on the conclusion that DCVG and DCVC, which are weakly active renal toxicants and genotoxicants, are formed in toxicologically significant concentrations following human exposures to TCE. This conclusion rests primarily on studies in which a relatively high blood DCVG concentration (100 nM) was observed in volunteers exposed for 4 hours to 50 or 100 ppm TCE. However, Lash et al. (1999) relied on a spectrophotometric chromatographic method analysis of TCE glutathione conjugate-derived metabolites which had substantial potential for detection of non-TCE-specific endogenous substances.

85	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health
86	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health

2.4.2.2
2.4.2.2

In a published paper sponsored by HSIA (abstract attached as Appendix 3), the HPLC/UV method used by Lash et al. (1999) was found to overestimate the levels of DCVG in blood, liver, and kidney compared to the more specific and reliable HPLC/MS/MS method. The reason for this overestimation was an interfering peak that was primarily from endogenous glutamate. It is imperative that the analytical data used in human health risk assessments be as accurate and reliable as possible, particularly if those data are used as surrogates for exposure to estimate potential health effects in humans. Our findings suggest that DCVG formation may have been substantially overestimated based on the levels that were quantified by the HPLC/UV method. The implications of this apparent uncertainty are that the GSH pathway may play a more limited role, if any, in kidney toxicity from TCE exposure; and that the risk of kidney toxicity and carcinogenicity from TCE exposure, particularly in humans, may be overestimated and may be occurring by alterative mode(s) of action not inclusive of reactive GSH-derived metabolites.
Since the publication of the IRIS Assessment in 2011, additional studies have evaluated the kidney concentrations of the oxidative and glutathione conjugate-derived metabolites of TCE in a variety of mouse strains administered five daily oral doses of 600 mg/kg TCE. Metabolites were quantitated two hours after the last daily dose; this time point was chosen because previous studies had shown that the approximate maximum plasma concentrations of TCA, DCA, DCVG and DCVC occurs two hours after an oral dose of TCE. Using a structure-specific HPLC-ESI-MS/MS method, Yoo et al. (2015) demonstrated that DCVG and DCVC were only a very small fraction of total metabolites quantitated in kidney. Trichloroethanol (TCOH) kidney concentrations were 2- to 4-fold greater than TCA, and TCA concentrations were 100- to 1,000-fold greater than DCA. Importantly, DCA concentrations were 100- to 1,000-fold greater than either DCVG or DCVC, resulting in the conclusion that TCE oxidative metabolism was up to five orders of magnitude greater than glutathione conjugate-derived metabolism.

87	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health
88	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Human Health

2.4.2.2
2.4.2.2

These findings were consistent with the earlier report from Kim et al. (2009), in which the time course of TCA, DCA, DCVG, and DCVC in serum was investigated following a single oral dose of 2,100 mg/kg TCE dose to male B6C3F1 mice. The total area under the curve (AUC) of TCA and DCA (oxidative metabolites) was 40,000-fold higher than the total AUC of DCVG and DCVC (glutathione conjugates). It should be noted that this study did not quantify the oxidative metabolite TCOH, which would have further increased the disparity of glutathione conjugate-derived metabolites relative to the oxidative-derived metabolites. These data demonstrate a dramatically lower function for glutathione-conjugate metabolism relative to oxidative metabolism in mice, despite the observation by Dekant (2010) (attached as Appendix 4) that mice generate DCVC at slightly higher rates than rats and greater than 10-fold higher than humans.
The results of studies using structure-specific analytical methods for quantitation of DCVG and DCVC directly challenge the hypothesis that glutathione conjugate-derived metabolites plausibly account for the genotoxicity, renal cytotoxicity, and ultimate carcinogenicity in rodents. DCVC was only marginally cytotoxic (LDH release), if at all, when incubated at 0.2M (200,000 nM) with isolated renal cortical cells of male and female rats. This in vitro concentration is substantially higher than the approximate maximum kidney concentrations of 10 to 75 nM DCVC reported in various strains of mice given a high oral dose of 600 mg/kg TCE for 5 consecutive days (Yoo et al., 2015). A likely No-Observed-Adverse-Effect-Level (NOAEL) of 1 mg/kg-day was also reported for kidney toxicity in mice administered DCVC orally or intraperitoneally at a dose of 1, 10 or 30 mg/kg, once a week for 13 weeks, as indicated by a lack of change in serum blood urea nitrogen (BUN), weak tubule dilation, and no signs of necrosis. If, based on the data from Yoo et al. (2015), it is assumed that the ratio of formation of oxidative metabolites to glutathione conjugate-derived metabolites is 10,000:1, an implausibly high (occupational or general population) dose of 6,044 mg/kg TCE would be required to deliver a NOAEL dose of 1 mg/kg-day DCVC (1 mmol/kg-day TCE results in 0.0001 mmol/kg/day DCVC; 1 mg/kg-day DCVC = 0.0046 mmol/kg-day). These dose-toxicity calculations suggest that it appears toxicologically implausible that real-world exposures to TCE are capable of producing doses of DCVC sufficient to cause renal toxicity and carcinogenicity in mice.

89	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Exposure
90	EPA-HQ-OPPT-2016-0737-DRAFT-0102_HSIA	6	Editorial

2.3.5, 2.6.1
A.1

IV. Miscellaneous. A. Worker and consumer exposure assessments should utilize all industry provided and publicly available information. The problem formulation document states that EPA will evaluate worker exposures to trichloroethylene in the TSCA risk evaluation from data that are publicly available, i.e, monitoring data from government agencies such as OSHA and NIOSH and from the published literature. It is recognized that these data may be from limited conditions of use or from out-or-date use/exposure scenarios. Thus, HSIA is submitting worker air monitoring data from trichloroethylene manufacturing facilities (attached as Attachment 5). We encourage EPA to utilize all available industry provided and publicly available information in its analysis of the exposure assessment in the risk evaluation.
B. Trichloroethylene is subject to transportation regulations by the Department of Transportation (DOT) and the Pipeline and Hazardous Materials Safety Administration (PHMSA). Appendix A.1 of the problem formulation document lists the federal laws and regulations to which trichloroethylene is subject. There are also specific transportation regulatory requirements for trichloroethylene by the DOT and PHMSA; these regulations need to be added to the list of Federal Laws and Regulations in Appendix A.1. The DOT regulations provide instructions on trichloroethylene is to be transported by air, highway, rail or water. It defines the operational measures to ensure the health and safety of workers, as well as to ensure that no product is allowed to be released into the air, soil or water. PHMSA has the responsibility to maintain the hazardous material regulations. We hope that these comments will be useful to EPA as it develops the risk evaluation for trichloroethylene.

91	EPA-HQ-OPPT-2016-0737-DRAFT-0104_Arkema	1	Exposure
92	EPA-HQ-OPPT-2016-0737-DRAFT-0104_Arkema	1	Other
93	EPA-HQ-OPPT-2016-0737-DRAFT-0104_Arkema	1	Exposure

2.2.2
2.2.2
2.2.2

Arkema is submitting the following information in regards to the Agency problem formulation efforts with respect to the Feedstocks that Arkema uses in the closed system manufacture of certain fluorinated gases in the US. Arkema believes that based on the totality of available evidence (industry provided and publicly available) it is appropriate for the Agency to exercise its discretion to exclude from its risk evaluation the use of the Feedstocks in the closed system manufacture of fluorinated gasses in the US because such activities pose only a de minimis exposure to humans or the environment. It appears that in making their determination, the Agency relied solely upon publicly available information and did not consider industry information that provides additional, important details about operations and use. Arkema, therefore, respectfully and strongly urges EPA to rely on all available data (industry provided and publicly available information) in making its exposure assessments – both in the problem formulations and in its risks evaluations.
General Overview: The Feedstocks are used as intermediate raw materials in the synthesis of certain fluorinated gases. Specifically, DCM is used in the manufacture of Difluoromethane (CAS No. 75-10-5) (F-32). TCE is used in the manufacture of 1,1,1,2-Tetrafluoroethane (CAS No. 811-97-2) (R-134A). The Feedstocks are reacted with other raw materials in closed systems to create various fluorinated gasses. In this process, the Feedstock molecule is transformed during the formation of the new fluorinated gas. The fluorinated gasses are used as refrigerants (F-134A & F-32), foam blowing agents (F-134A and F-32) and solvents (F-32). Arkema uses the Feedstocks at its Calvert City, Kentucky facility solely for industrial purposes.
Arkema provided the Agency with an extensive description of our operations in connection with the use of the Feedstocks, including information regarding Arkema employee air monitoring, employee biomonitoring, ambient air monitoring, and emissions releases. To date, it appears that the data we provided was not considered during the exposure assessments. By not considering this additional information, the Agency is not taking into account all provided data sets, and the resulting actions will be incomplete and could significantly overestimate the potential exposures posed by Feedstock use in closed systems.

94	EPA-HQ-OPPT-2016-0737-DRAFT-0104_Arkema	1	Exposure
95	EPA-HQ-OPPT-2016-0737-DRAFT-0104_Arkema	1	Exposure

2.2.2
2.2.2

Utilize All Avaiblable Data to Make Exposure Assessment: We urge the EPA to utilize the information that we and others in the industry provided and to use this information in addition to, and in conjunction with, publicly available information. The information provided by Arkema and the industry includes data on employee air monitoring, ambient air monitoring, biomonitoring, and emissions releases, and it does not appear that these important factors were considered when making the determination formulations. EPA appears to have aggregated exposure data across uses and such aggregation will yield greatly divergent exposure profiles – from completely emissive (solvent use) to closed systems (feedstock use). It is unclear whether EPA will do the same aggregation for the risk evaluations, and if the same methodology is used during the risk evaluations, it further increases the risk of overestimation of potential exposures posed by Arkema's use of the Feedstocks in closed systems.
Conclusions. Based upon the totality of actual human and environmental exposure data (public and industry data) provided to the Agency, Arkema believes that the Agency has adequate and appropriate information to exercise its discretion not to include the use of TCE and DCM in the closed system manufacture of fluorinated gasses in the scope of its risk evaluations for these substances. As indicated above, industry evidence should be given equal weight as publicly available information. Industry often has resources at their disposal, that are unavailable to authors of much of the publicly available information and such information is necessary to complete an accurate picture of the risk of exposure to certain substances. If the Agency continues to include Arkema's use in its risk evaluation, Arkema strongly urges the Agency to utilize all available information, including information provided by industry, in conducting EPA's risk evaluations. Arkema appreciates the opportunity to provide written comments to the Office of Pollution Prevention and Toxics (OPPT) regarding rulemaking on problem formulations for the risk evaluations to be conducted under the Toxic Substances Control Act, and general guiding principles to apply systematic review in TSCA risk evaluations.

96	EPA-HQ-OPPT-2016-0737-DRAFT-0109_tire-manufacturers	1	General
97	EPA-HQ-OPPT-2016-0737-DRAFT-0109_tire-manufacturers	1	Other

N/A
2.2.2

I. Introduction The U.S. Tire Manufacturers Association (USTMA) is the national trade association representing major tire manufacturers that produce tires in the United States, including Bridgestone Americas, Inc., Continental Tire the Americas, LLC; Cooper Tire & Rubber Company; The Goodyear Tire & Rubber Company; Kuhmo Tire Co., Inc.; Michelin North America, Inc.; Pirelli Tire North America; Sumitomo Rubber Industries, Ltd.; Toyo Tire Holdings of Americas Inc. and Yokohama Tire Corporation. Effective May 23, 2017, the Rubber Manufacturers Association officially changed its name to the U.S. Tire Manufacturers Association (USTMA). USTMA members are committed to effective implementation of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA) and support a robust federal process for assessing chemicals in commerce. USMTA thanks EPA for the opportunity to provide comments on the problem formulation for TCE and the opportunity to share accurate use information with the agency about this substance. TCE is not used by USTMA member companies in the process of manufacturing tires, in tire manufacturing facilities, in tire retread facilities, or in USTMA member company retail and service center facilities.
II. Overview of the problem formulation and market and use report for TCE. EPA's problem formulation document and market and use report for TCE outlines the conditions of use the agency plans to review during the risk evaluation for TCE. The market and use report includes two uses of TCE in tires: (1) as a processing solvent in the production of an antioxidant for tire manufacturing and (2) as a tire repair cement and solvent. [U.S. Environmental Protection Agency, Trichloroethylene Market and Use Report, March 2017]. USTMA surveyed our members and confirms that TCE is not found in antioxidants used by USTMA members to manufacture tires and is not used by USTMA member companies in the process of manufacturing tires, in tire manufacturing facilities, or in tire retread facilities. Additionally, USTMA surveyed members regarding the use of TCE in tire repair cements and solvents and can confirm that member companies that operate retail facilities and service centers do not use TCE in tire repair cements and solvents.

98	EPA-HQ-OPPT-2016-0737-DRAFT-0109_tire-manufacturers	1	Other/Exposure
99	EPA-HQ-OPPT-2016-0737-DRAFT-0109_tire-manufacturers	1	Exposure, Policy

Apx C-1, Apx D-1
2.2.2, 2.5

III. General comments on EPA's approach to problem formulations. A. Supporting tables. USTMA appreciates the supporting tables in the appendices for the various problem formulations for the first ten chemicals EPA will review. For TCE, these are "appendix C - SUPPORTING TABLES FOR INDUSTRIAL AND COMMERCIAL ACTIVITIES CONCEPTUAL MODEL" and "appendix D -SUPPORTING TABLE FOR CONSUMER ACTIVITIES AND USES CONCEPTUAL MODEL." These tables clearly communicate the uses of a chemical and the various routes of exposure EPA will assess in risk assessment. USTMA encourages the agency to continue use of these tables in problem formulation documents.
B. Conditions of use. USTMA supports EPA's exclusion of uses outlined in the market and use report that are either past uses or uses that the agency does not have enough information to confirm the use of a substance. However, USTMA questions EPA's approach for each of the first ten chemicals to exclude certain exposure pathways that are under the jurisdiction of other regulatory programs; specifically, the Clean Water Act (CWA). USTMA encourages EPA to assess the scope of the CWA in regulating non-point sources. USTMA supports a robust federal approach to review aquatic routes of exposure versus a state-by-state approach for addressing non-point sources. Additionally, the problem formulation documents specify that EPA "may exclude conditions of use that the Agency has sufficient basis to conclude would present only de minimis exposures or otherwise insignificant risks (such as in a closed system that effectively precludes exposure or as an intermediate.)" U.S. Environmental Protection Agency, Document #EPA-740-R1-7014, Problem Formulation of the Risk Evaluation for Trichloroethylene (May 2018) at 19. USTMA encourages EPA to ensure the preemptive effect of TSCA by providing a safety determination for de minimis uses. For example, EPA could conclude that there is no unreasonable risk presented by the de minimis use of a chemical substance because the substance is in a closed loop system, a chemical intermediate or an impurity.

100	EPA-HQ-OPPT-2016-0737-DRAFT-0109_tire-manufacturers	1	Exposure
101	EPA-HQ-OPPT-2016-0737-DRAFT-0109_tire-manufacturers	1	General/Exposure
102	EPA-HQ-OPPT-2016-0737-DRAFT-0111_UAW	1	General

2.2.2
2.2.2
N/A

C. "Fit for purpose" The problem formulations for the first ten chemicals specify that each risk evaluation will be "fit-for-purpose," meaning that "not all conditions of use will warrant the same level of evaluation and the Agency may be able to reach some conclusions without comprehensive or quantitative risk evaluations." (Problem formulation for TCE at Page 13). USTMA supports a screening level approach to risk evaluation and conclusion that "not all conditions of use will warrant the same level of evaluation." We also support the agencies decision to "reach conclusions without comprehensive or quantitative risk evaluations." USTMA encourages EPA to issue safety determinations for uses as they are made by the agency. We support and encourage the agency to issue safety determinations about uses that do not pose a risk early in the risk evaluation process.
IV. Conclusion. USTMA thanks EPA for the opportunity to provide comments on the problem formulation process and accurate information on the use of TCE, one of the first ten chemicals under review through the Toxic Substances Control Act as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.
The International Union, UAW, representing one million active and retired members is grateful for the opportunity to comment on the above referenced document.

103	EPA-HQ-OPPT-2016-0737-DRAFT-0111_UAW	1	Exposure, Editorial
104	EPA-HQ-OPPT-2016-0737-DRAFT-0111_UAW	1	Exposure

2.5.3.1-3, Appendix C
2.3.5.1

Inclusion and Further Analysis The UAW finds this document to be confusing. A literal reading of the document would suggest that the only pathway that EPA plans to include and further analyze in risk evaluation is aquatic species (i.e. aquatic plants) exposed via contaminated surface water. This is the only pathway mentioned in Section 2.5.3.1 whose title suggests it covers all such pathways. In addition, no occupational pathways are mentioned in 2.5.3.2 Pathways that EPA Plans to Include but Not Further Analyze. Nor are they mentioned in 2.5.3.3 Pathways that EPA Does Not Plan to Include in the Risk Evaluation. In fact, one can read the entire body of the document without getting any idea of whether EPA plans to analyze occupational exposures or not. The only indication in the entire document as to EPA's intentions is the column header in Appendix C entitled "Proposed for Further Risk Evaluation." The UAW takes it to be the case that wherever there is a "Yes" in this column, further risk evaluation will be done. The UAW requests that this document be revised with at least one additional sentence in Section 2.5.3.1 stating that all occupational pathways with a "Yes" in the appropriate column in Appendix C will be further analyzed.
Occupational Non-Users EPA states [p.39] "Occupational non-users are not directly handling TCE; therefore, skin contact with liquid TCE is not expected for occupational non-users, but skin contact with vapors is expected for occupational non-users." Based on this conclusion, Appendix C excludes a large number of Release/Exposure scenarios involving dermal contact of occupational non-users (ONU) with liquid TCE. It is unclear from the description of ONU whether workers performing maintenance activities on TCE contaminated equipment are considered by EPA to be workers or ONU.

105	EPA-HQ-OPPT-2016-0737-DRAFT-0111_UAW	1	Exposure
106	EPA-HQ-OPPT-2016-0737-DRAFT-0111_UAW	1	Exposure, Editorial

2.3.5.1
2.3.5.1

The UAW strongly urges EPA to do one of the following: 1. Treat workers performing maintenance activities on TCE contaminated equipment as workers so that their dermal contact with TCE will be further analyzed OR 2. Reanalyze the following Release/Exposure scenarios to determine whether or not the ONU might include workers performing maintenance activities on TCE contaminatedequipment and include these scenarios in further analysis when and where they do: -TCE Manufacture - TCE as by-product - Manufacture of HFC's, HCL and muriatic acid - Manufacture of large, rigid plastic products - Industrial textile dyeing; and industrial textile finishing - Formulation of aerosol and nonaerosol products - Repackaging of import containers - Recycling of Process Solvents Containing TCE - Repackaging into large and small containers - Degreasing - Battery coat; and soap, cleaning compound, and toilet preparation manufacturing - Recovery of wax and paraffin from refuse; tin recovery from scrap metal; and phenol extraction from wastewater - Precipitant for beta-cyclodextrin manufacture - Disposal of TCE wastes
In addition, EPA states that it does not intend to evaluate further dermal or inhalation exposure to TCE liquid or vapor for workers or ONU who work in the distribution of TCE-containing formulated products and/or of bulk TCE shipments because these exposures will be assessed during other lifecycle stages such as loading and unloading. It is not transparent where and how these exposures will be assessed. The UAW requests that EPA revise the document to make this information available in a transparent manner.

107	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	General, Editorial
108	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure

N/A
2.2.2, 2.3.5

For example, Trichloroethylene (TCE) and Tetrachloroethylene (PERC) are among the most well-studied chemicals and are among those pollutants most prevalent in groundwater in the U.S. and elsewhere. It appears that the only difference between the scoping document and the Problem Formulation documents for these chemicals is that they have "refined" the conditions of use and exposure pathways, eliminating certain conditions of use and exposure pathways from consideration. It is unclear why these changes warranted a whole new document that impedes transparency, as it is difficult for the public to compare the Problem Formulations to the 2017 scope in order to understand the differences. It would be more helpful and easier for the public to understand any differences if EPA simply called the Problem Formulations amended scoping documents, rather than giving them new names and formats, insofar as scoping is an accepted mechanism to formulate problems for consideration in analysis.
TSCA also does not adequately address legacy uses of PERC, methylene chloride, carbon tetrachloride, and TCE, as well as bystander exposure to PERC.17 These chemicals are possible or probable human carcinogens and toxic to various organs including the kidney and liver. They are very frequently found in groundwater and soil vapor throughout the City. This "legacy" directly impacts many New Yorkers due to widespread historic (and often current) use and the dense urban environment. These chemicals enter buildings through the soil vapor and frequently cause residents to breathe concentrations that are well above health-based guidance values. However, the extent of this problem is poorly studied and not adequately addressed byany federal acts. Because whole buildings or neighborhoods are sometimes affected, attempting to remediate these chemicals after they have entered into groundwater and soils is expensive and time consuming, and occurs only after building occupants, including children, are exposed to them. In order to prevent human health consequences, and an extraordinary waste of resources, TSCA must regulate them before they are legacy pollution.

109	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure
110	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure
111	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure

2.2.2, 2.3.5
2.3, 2.6.1.1
2.3, 2.6.1.1

By disregarding the risks of legacy uses of all 10 chemicals, most importantly asbestos, PERC, methylene chloride, carbon tetrachloride, and TCE, EPA is excluding from its consideration the means by which many Americans may be exposed to these hazardoussubstances, and undercounting the net risks of exposure for all Americans.
3. TCE Exposure Pathways First, EPA's proposal to exclude from further analysis the risks of TCE exposure caused by land application of biosolids is based on incomplete and incorrect information. [p. 53 of PF] Instead of basing the exclusion on removal efficiencies and the physical chemical properties of TCE, in the City's opinion, EPA should consider whether TCE is present in biosolids based on data. TCE has been historically present in biosolids in the parts per million range, but thanks to EPA regulation, pollution prevention measures, and other efforts and changes in use patterns, TCE is largely currently present in biosolids in only trace amounts, if at all. Therefore, while there may be no current pathway (so long as EPA regulation, pollution prevention measures, and other efforts and changes in use patterns remain effective in minimizing and working to eliminate TCE in wastewater and other processes that generate biosolids) should TCE contamination in biosolids become prevalent again, EPA should be required to consider exposure caused by land application of biosolids.
Generally, before determining that a pathway for a given media is not an exposure risk, EPA should cite data regarding the chemical's presence or absence in the media of potential concern and revisit that determination to ensure that future exposures do not arise. Additionally, minimal risk levels can change over time. Following heightened concern about Per- and Polyfluoroalkyl compounds (PFAS) caused by the documented presence of PFAS in biosolids and in surface waters and soils following biosolid applications, EPA reduced its Health Advisory for PFASs to the 70 part per trillion range. Should EPA reduce advisory levels for any chemicals regulated under TSCA, EPA should be required to revisit exposure pathways that had earlier been discounted because of a chemical's minimal presence.

112	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure, RegNex
113	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure, RegNex

Figures 2-2 through 2-4
Figures 2-2 through 2-4

Second, EPA's rationale for excluding from consideration certain exposure pathways caused by direct releases and wastes from industrial, commercial, and consumer uses and the receptors that may encounter those exposure pathways and directly ingest contaminated water is flawed, or at least inadequately supported. The conceptual models presented in figures 2-2 through 2-4 of the TCE Problem Formulation assumes that wastewater or liquid wastes receive treatment from a wastewater treatment plant (WWTP) and that any direct impacts through an oral route are addressed by Safe Drinking Water Act (SDWA) regulations. Specifically, EPA states that "the drinking water exposure pathway for trichloroethylene is currently addressed in the SDWA regulatory analytical process for public water systems, EPA does not plan to include this pathway in the risk evaluation for trichloroethylene under TSCA."[p. 54 of PF for TCE]
The City disagrees with this exclusion for several reasons. First, at least with respect to consumer uses, not all consumer wastewater discharges to WWTPs. For example, in Suffolk County on Long Island, New York, which relies on water supply from a sole source aquifer and where there are private wells and over 350,000 septic systems, consumer or commercial use of TCE products may result in a direct discharge of TCE to groundwater that potentially impacts drinking water through private wells and community water supplies. The SDWA cannot not adequately address these exposures—the appropriate statute for minimizing TCE exposures in areas without WWTPS is TSCA. Second, the SDWA contains provisions for both an enforceable standard, the maximum contaminant level (MCL), as well as a goal for health protection—the maximum contaminant level goal (MCLG). MCLs are to be set as close to the MCLG as possible while also considering the economic feasibility of reaching the MCLG. In the case of TCE, the MCLG is zero, but the MCL (5 µg/L) was developed considering the practical quantitation limit at the time it was being promulgated, and is subject to a six year review and recommendation for reassessment.

114	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure, RegNex
115	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure

Figures 2-2 through 2-4
2.2.2, 2.3.5

Therefore, while the SDWA may prevent exceedances of the MCL, TSCA regulation is necessary to continue to advance toward the MCLG of zero or future MCLs that are established based on our future ability to detect smaller levels of contamination. Third, EPA is including in the analysis in Figure 2-4 the impact of releases on aquatic species. However, the Clean Water Act directs EPA to establish ambient water quality criteria for the protection of human health through direct consumption of surface water and for direct consumption of human health and aquatic organisms. Therefore, the inclusion of this exposure pathway contradicts the justification EPA set forth for excluding other pathways-that other statutes are effective in addressing the potential exposure. The City is not suggesting that the impact of TCE via water on aquatic species should be not be further analyzed, instead the City believes that all pathways caused by "activities that EPA concluded do not constitute conditions of use" and legacy uses must be included.
A. The City's Substantive Concerns The Problem Formulations relate to ten different chemicals used across a spectrum of applications and industries, many of which (including, Methylene chloride, Perchloroethene, and Trichloroethene) are used frequently in the City in facilities that, because of our dense urban environment, are co-located in or adjacent to buildings where other people, including sensitive receptors, use the buildings for residential or commercial purposes. Others are currently used with less frequency, but off-gas into the air of buildings because they are present in soil vapor or groundwater (for instance, Carbon tetrachloride and 1-Bromopropane). For instance, dry cleaners are often in residential buildings where children may live or be cared for, or next to schools. Often, these chemicals are used in mixed-use zoning districts where residential and commercial uses are permitted to exist adjacent to or co-located with manufacturing uses. Because of these uses, the City is concerned about the limitations that EPA has set forth in the Problem Formulations that exclude from consideration certain exposure pathways. [Attachment A; comments dated 7/13/18]

116	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure

2.2.2, 2.3.5

First, the City has significant concerns about EPA's decision to remove from the risk evaluation certain activities and exposure pathways, including "activities that EPA concluded do not constitute conditions of use." [p. 21 of PF for PERC] This limitation deviates from the scope set forth in the June 2017 Scopes of Risk Evaluation, [Scope for PERC] which stated that EPA intended to "assess each use subcategory by identifying all potential sources of release and human exposure associated with that subcategory." [pp. 20-21 of Scope for PERC] By excluding activities and uses that are designated on a case by case basis as not constituting conditions of use,4 EPA will likely fail to consider potential exposures caused during manufacture and use of the product, such as accidental spills, or exposures that occur when the chemical is used properly when the facility is co-located with or adjacent to residential, educational, recreational, or commercial activities. For example, using trichloroethene (TCE) as a spot remover in a co-located dry cleaning facility on the ground floor may result in a resident on the floor above the facility being exposed to the TCE. [Attachment A; comments dated 7/13/18]

Footnote:

4 "Conditions of use" are defined by the Administrator and he or she has the authority to exclude conditions on case-by-case basis.

117	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure

2.2.2, 2.3.5

New York City has significant soil vapor exposure resulting from extensive use of Carbon tetrachloride, Methylene chloride, Perchloroethene, and Trichloroethene6 within our borders. This contamination results in health consequences not only for workers in the source facility, but also for adjacent or co-located workers, residents, and children. By curtailing TSCA, there will be further opportunities for these chemicals to enter the soil, air, groundwater, and buildings, exposing nearby New Yorkers and requiring unnecessary remediation in the future. [Attachment A; comments dated 7/13/18]

Footnote:

6 Note, while 1-Bromopropane is not often found in City soil vapor. However, if 1-Bromopropane becomes more widely used (e.g., as a replacement solvent for PCE in dry cleaning) then it would likely be more abundant in the soil vapor. The City is hopeful that TSCA risk evaluators will consider the full implications of 1-Bromopropane and its potential for being a future contaminant. Additionally, if chlorinated compounds are replaced with brominated solvents, then other common workplace exposures to brominated solvents will likely increase in the future because the workplace practices are unlikely to change. The City recognizes that in the 1-Bromopropane Problem Formulation, EPA discusses inhalation of the chemical by people occupying businesses co-located with dry cleaners, and states that EPA will consider various issues relating to the chemical's waste, disposal, and use that may impact other non-occupational bystanders. However the Problem Formulation does not specifically discuss the inhalation of 1-Bromopropane in co-located homes.

118	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure, PESS

2.2, 2.3.5

The wide variety of chemicals to which construction workers are exposed is evident from a pilot study completed by CPWR - The Center for Construction Research and Training in January 2018. The pilot study asked 196 safety and health trainers from four different construction unions to identify common chemical hazards encountered in their trades. The trainers identified 63 different common chemical hazards in their trade, including some of the priority chemicals. The results were instructive, as they revealed not only the large numbers and wide range of chemicals which construction workers regularly encounter, but they showed that even these well-informed trainers did not necessarily know which specific chemicals are present in the products they use. For example, while almost two thirds of trainers listed adhesives as a common hazard, less than one fifth reported 1-bromopropane, methylene chloride, perchloroethylene, or trichloroethylene as a common hazard, even though these chemicals are known components of some adhesives.

119	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure, Policy, RegNex
120	EPA-HQ-OPPT-2016-0737-DRAFT-0113_CEH	1	General

2.5
N/A

In addition to air and water, EPA has decided not to consider exposures arising from wastes, specifically stating that "EPA does not expect to include on-site releases to land from industrial non-hazardous and construction/demolition waste landfills". See e.g., Problem Formulation Document for 1-BP at 55, Problem Formulation Document for 1,4-dioxane at 45, Problem Formulation Document for TCE at 56, Problem Formulation Document for methylene chloride at 56, Problem Formulation Document for NMP at 51, Problem Formulation Document for PERC at 62. EPA justifies excluding this pathway from its risk assessment because wastes are primarily regulated under state programs, while also acknowledging that not all states require the same waste disposal protections. Yet, construction workers are routinely involved in handling, storage, and transporting waste materials that potentially contain the priority chemicals. All fourteen building trades unions participate in hazardous waste operations and emergency response (HAZWOPER) activities and Department of Energy site construction and remediation. Removal and disposal tasks can involve cutting, abrading, grinding, demolishing, digging, crushing, loading, and unloading resulting in exposure. It is only by first assessing whether these chemicals pose an unreasonable risk, and then by examining whether the state programs sufficiently address those risks that EPA can satisfy its statutory mandate to decide whether further regulation is required. See §6(a).
On behalf of our 36,000 supporters, the Center for Environmental Health is pleased to submit the following comments about the "Problem Formulation of the Risk Evaluation for Trichloroethylene." We believe that the Environmental Protection Agency needs to make significant improvements if this process is to protect public health and be consistent with the Frank R. Lautenberg Chemical Safety for the 21st Century Act. We describe these improvements below.

121	EPA-HQ-OPPT-2016-0737-DRAFT-0113_CEH	1	Human Health
122	EPA-HQ-OPPT-2016-0737-DRAFT-0113_CEH	1	Exposure, PESS
123	EPA-HQ-OPPT-2016-0737-DRAFT-0113_CEH	1	Human Health, PESS

2.4.2.1, 2.6
2.3
2.3.5, 2.5, 2.6

1. The problem formulation must include endocrine disruption as a noncancer hazard in Sec. 2.4.2.1. Hormone disrupting chemicals (endocrine disruptors) are a significant public health concern because some cause adverse effects at environmentally relevant exposures. For an example of trichloroethylene acting as an endocrine disruptor, see Kanada, M; Miyagawa, M; Sato, M; Hasegawa, H; Honma, T. (1994). Neurochemical profile of effects of 28 neurotoxic chemicals on the central nervous system in rats (1) Effects of oral administration on brain contents of biogenic amines and metabolites. Ind Health 32: 145-164. EPA's Chemistry Dashboard notes that "no endocrine disruption relevant data" is currently available for trichloroethylene. This data gap must be filled.
2. The problem formulation must require aggregate exposure assessments that include exposures caused by conditions or products not regulated by TSCA. While exposures from current use of products is important, exposure assessments must include aggregate exposure via contaminated water, soil and air, and products that are no longer manufactured but are still in use, regardless of the source of this contamination. Aggregate exposure assessment is widely used in risk assessment. Failure to use an aggregate exposure assessment could significantly underestimate exposure, including the exposure to vulnerable subpopulations. The use of aggregate exposure assessment was recommended to the Environmental Protection Agency by the agency's Children's Health Protection Advisory Committee.
3. The problem formulation must require use of lifestage analysis when assessing risks to children. Each stage of childhood and adolescence differs from each other and from adults in significant ways. Lifestage analysis incorporates differences in anatomy, physiology, toxicokinetics, diet, environment, and behaviors that are relevant in a risk assessment. The Environmental Protection Agency developed a framework for lifestage analysis in 2006 and the use of lifestage analysis was recommended to the Environmental Protection Agency by the agency's Children's Health Protection Advisory Committee.

124	EPA-HQ-OPPT-2016-0737-DRAFT-0113_CEH	1	Human Health, PESS
125	EPA-HQ-OPPT-2016-0737-DRAFT-0113_CEH	1	General
126	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General

2.4, 2.6
N/A
N/A

4. The problem formulation must require complete testing for neurotoxicology and developmental toxicology. EPA's Chemical Dashboard notes that there currently is "no developmental toxicity data available" for trichloroethylene. Similarly, there is "no neurotoxicology data available." Both types of data are important, and critical for assessing risks to children, a vulnerable subpopulation. The need for these types of data was highlighted by the Children's Health Protection Advisory Committee.
6. The problem formulation must require use of Integrated Risk Information System assessments when available. Trichloroethylene was comprehensively assessed by IRIS in 2011. This assessment should be the basis of the current process.
• Six of the 10 chemicals – asbestos (and Libby amphibole asbestos), trichloroethylene (TCE), methylene chloride (MC), carbon tetrachloride (CTA), perchloroethylene (PERC) and 1,4-dioxane – have been assessed under the EPA Integrated Risk Information System (IRIS). The IRIS process is the Agency's authoritative mechanism for reviewing available studies and characterizing the health effects of chemicals. The problem formulations, however, indicate that EPA will revisit the interpretation of studies already evaluated in IRIS using its highly questionable TSCA "systematic review" method that has not been peer reviewed. This may lead to departures from IRIS determinations of the "best available science" and "weight of the evidence." Reopening IRIS findings would harm the public by prolonging uncertainty on issues that have been addressed and resolved through an authoritative and transparent process. In rare cases where significant new data (since the IRIS assessment) are available, the EPA TSCA program should rely on the IRIS program to review, assess, and if appropriate incorporate any new information using a systematic review method that is consistent with the state of the science. (Section X, pages 25-28)

127	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Human Health
128	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Human Health

2.4.2
2.4.2

TCE. Trichloroethylene was evaluated well over a decade ago, in 2004, by the EU, which at the time identified the need for developmental neurotoxicity testing to be conducted for TCE: " The developmental toxicity of inhaled trichloroethylene at non-maternally toxic levels (up to 1,800 ppm) has been investigated in rats, mice and rabbits in conventional studies. No evidence of developmental toxicity was reported. In contrast, the results of a series of non-standard oral studies in rats raised some concerns about the potential for trichloroethylene to induce developmental neurotoxicity at dose levels in the range of 30-110 mg/kg/day. However, these studies were of limited scope and were considered not to provide sufficient basis on which to draw clear conclusions about the hazardous properties of trichloroethylene. To be able to draw clear conclusions regarding developmental neurotoxicity, further testing according to the draft OECD TG 426 Developmental Neurotoxicity guideline would be required.”
The 2011 IRIS assessment comes to similar conclusions, also identifying the potential for developmental neurotoxicity and noting this data gap: "In summary, an overall review of the weight of evidence in humans and experimental animals is suggestive of the potential for developmental toxicity with TCE exposure. A number of developmental outcomes have been observed in the animal toxicity and the epidemiological data, as discussed below. These include adverse fetal/birth outcomes including death (spontaneous abortion, perinatal death, pre- or post-implantation loss, resorptions), decreased growth (low birth weight, SGA [small for gestational age], IUGR [intrauterine growth restriction], decreased postnatal growth), and congenital malformations, in particular cardiac defects. Postnatal developmental outcomes include developmental neurotoxicity, developmental immunotoxicity, and childhood cancer."

129	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Human Health
130	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy
131	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy

2.4.2
N/A
N/A

The TCE problem formulation identifies the risk of neurotoxicity and developmental toxicity separately, noting evidence from both human studies and animal studies, including psychomotor effects from TCE exposures. Yet, there is no study that specifically targets the sensitive and critical endpoint of developmental neurotoxicity. The failure to address the risks of developmental neurotoxicity posed by TCE represents a serious data gap in EPA's assessment, particular for the low-dose risks.
X. EPA Should Not Revisit Definitive Findings in IRIS Assessments Unless There Are New Data That Inform EPA's Evaluation of the Weight of the Evidence Six of the 10 chemicals -- asbestos, TCE, MC, CTC, PERC and 1,4-dioxane -- have been assessed under the EPA Integrated Risk Information System (IRIS). The IRIS process is the Agency's authoritative mechanism for reviewing available studies, characterizing the health effects of chemicals and identifying concentrations below which these chemicals are not likely to cause adverse effects. IRIS assessments typically reflect years of work by EPA scientists, multiple rounds of public comment, inter and intraagency consultation, and extensive peer review, often by the Agency's independent Science Advisory Board (SAB) or the National Academy of Sciences (NAS). The IRIS program recently received a favorable review from the NAS.
XI. EPA Risk Evaluations Should Not Reassess Uses of TCE, MC And NMP That Were Fully Assessed In Its Proposed Section 6(a) Rules for These Chemicals EPA has proposed to ban certain uses of TCE, MC and NMP under section 6(a) of amended TSCA. As the basis for these proposed rules, EPA conducted comprehensive exposure and risk assessments on the targeted uses of the three chemicals and concluded that these uses presented unreasonable risks of injury under TSCA. The EPA assessments were subject to public comment and peer review both during their development and again as part of the rulemaking process. Although the EPA Administrator recently agreed to finalize the proposed MC ban, the problem formulations indicate that EPA will not rely on the completed assessments but will "reassess" the targeted uses for TCE and NMP. We strongly disagree with this approach.

132	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy, Human Health
133	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy, Human Health

N/A
2.4.2

In its peer reviewed IRIS assessment for TCE, EPA concluded that "[i]ncreased incidence of fetal cardiac malformations was identified as the most sensitive health endpoint within the developmental toxicity domain." This finding was reaffirmed in EPA 2014 TCE Work Plan Chemical Assessment. In 2016, EPA scientists published a systematic review of the data confirming the basis for linking TCE exposure to congenital heart malformations. Congenital heart effects can be disabling or even deadly. The significant and unreasonable risks posed by TCE in consumer and industrial products, particularly from exposures during pregnancy, led EPA to propose to ban its use in aerosol and vapor degreasing operations.
Despite EPA's repeated findings of heart malformations linked to TCE, the problem formulation states that: "The relevant studies will be evaluated using the data quality criteria in the Application of Systematic Review in TSCA Risk Evaluations document." This evaluation could result in EPA rejecting the peer-reviewed findings of earlier assessments. Significantly, at the same time as TSCA issued its systematic review guidance for public comment, an industry-sponsored consulting firm published its analysis of why the studies linking TCE with heart defects were "not sufficiently reliable for the development of toxicity reference values." Since the industry-sponsored publication uses reasoning similar to that in the flawed TSCA systematic review guidance, it seems likely that the TSCA risk evaluation may similarly dismiss the evidence of congenital heart defects. Disregarding this important scientific evidence of harm would put the public at great risk.

134	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Exposure

2.3

First, TSCA and the Occupational Safety and Health Act (OSH Act) apply differing standards of protection and the level of risk reduction afforded by OSHA limits may well be inadequate to satisfy the more stringent requirements of TSCA. OSHA is only authorized to adopt workplace standards for chemicals presenting "significant risks of harm," a term interpreted by the Supreme Court's Benzene decision as requiring OSHA to demonstrate by substantial evidence that "it is at least more likely than not that longterm exposure to [a chemical] presents a significant risk of material health impairment." By contrast, the term "unreasonable risk" under TSCA does not impose this high threshold for regulation. Further, OSHA may impose only economically and technologically feasible limits on exposure. However, economic and technological considerations have no bearing on EPA's determinations of unreasonable risk, which cannot take into account cost and other non-risk factors under section 6(b)(4)(A).80 Finally, while OSHA is only authorized to place limits on exposure, TSCA provides a broad array of remedies, including bans of production and use, which may provide a level of protection that OSHA lacks authority to impose.

Footnote: 80 Based on these considerations, EPA decided against referring to OSHA workplace risks from exposure to trichloroethylene (TCE) under section 9(a) of TSCA, even though OSHA had earlier promulgated a workplace standard for TCE. In deciding to address risks to workers through a section 6(a) rulemaking instead, EPA compared its authority under TSCA to eliminate these risks to that of OSHA, concluding that "there is no other federal law that provides authority to prevent or sufficiently reduce these . . . exposures." It further concluded that risks that EPA found to be "unreasonable" under TSCA might not be deemed "significant" by OSHA. 82 Federal Register 7432, 7454 (January 19, 2017).

135	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Exposure

2.3

Second, a number of the OSHA standards that apply to chemicals subject to the first 10 risk evaluations were developed many years ago and do not reflect current data and scientific understanding of the health effects of the regulated chemicals.81 Thus, the levels of exposure allowed by these standards may be unsafe when evaluated using the best available science.

Footnote:

81 OSHA has two types of standards. Under section 6(a) of the OSH Act, OSHA adopted hundreds of PELs in 1971 that were, at that time, considered national consensus standards. They have not been updated since and are based on science from the 1960s or earlier. Since 1971, OSHA has regulated only about 40 chemicals under section 6(b). These more comprehensive standards are based on thorough evaluation of health effects and a determination that risks are significant. OSHA has 6(b) standards regulating only asbestos and MC. It has PELs (adopted under 6(a)) for PERC and TCE but not for the other 10 chemicals. In the case of both asbestos and MC, OSHA's published Federal Register preambles found that even at the revised PEL, employees continued to be exposed to significant risks i.e., risks above 1/1000 – OSHA's definition of significant risk.

136	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure

2.2, 2.3

Finally, as EPA has recognized, some of the industrial hygiene strategies embodied in OSHA standards – such as labels and respirators – are known to be of limited effectiveness in protecting workers and have been required by OSHA to compensate for the lack of effective engineering controls or constraints on its authority, not because they are uniformly protective. For example, in its proposed section 6(a) rules for TCE, MC and NMP, EPA analyzed a universe of 48 studies [84] and concluded that: • [C]onsumers and professionals do not consistently pay attention to labels; consumers and professional users often do not understand label information; consumers and professional users often base a decision to follow label information on previous experience and perceptions of risk; even if consumers and professional users have noticed, read, understood, and believed the information on a hazardous chemical product label, they may not be motivated to follow the label information, instructions, or warnings; and consumers and professional users have varying behavioral responses to warning labels, as shown by mixed results in studies.

Footnote:

84 OPPT summarized these studies in a paper entitled: The Effectiveness of Labeling on Hazardous Chemicals and Other Products (March 2016) (Ref. 33 in rulemaking docket).

137	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure
138	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Exposure

2.2, 2.3
2.2, 2.3

Similarly, EPA cautioned that "there are many documented limitations to successful implementation of respirators," explaining that: "Not all workers can wear respirators. Individuals with impaired lung function, due to asthma, emphysema, or chronic obstructive pulmonary disease for example, may be physically unable to wear a respirator. Determination of adequate fit and annual fit testing is required for a tight fitting full-face piece respirator to provide the required protection. Also, difficulties associated with selection, fit, and use often render them ineffective in actual application, preventing the assurance of consistent and reliable protection, regardless of the assigned capabilities of the respirator. Individuals who cannot get a good face piece fit, including those individuals whose beards or sideburns interfere with the face piece seal, would be unable to wear tight fitting respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue and reduced work efficiency (63 FR 1156, January 8, 1998). According to OSHA, 'improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health. (63 FR 1189-1190)."
Because of these considerations, EPA cannot assume that, simply because they are required by OSHA standards, labeling or respirators will in fact provide adequate worker protection and successfully prevent unsafe exposure. Rather, as it did in its proposed rules for MC, TCE and NMP, EPA should explicitly recognize the limitations of these industrial hygiene controls and determine whether risks to workers are unreasonable given that labeling and respirators are often unprotective and unreliable in the real world.

139	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General
140	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, Exposure, Human Health

N/A
2.4, 2.5

The Chemical Products and Technology Division of the American Chemistry Council (ACC-CPTD)1 submits the enclosed comments on the problem formulation of the trichloroethylene (TCE) risk evaluation under the Toxic Substances Control Act (TSCA), as amended by the Lautenberg Chemical Safety Act (LCSA) enacted in June 2016. Footnote: 1 ACC represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. ACC's Chemical Products and Technology Division is composed of a wide range of more than 60 self-funded product and sector groups that are focused on specific chemistries and related technologies. Members participating in these groups include large and small manufacturers, formulators, downstream users, distributors, suppliers and other trade associations.
ACC-CPTD supports the approach to risk evaluation outlined in the draft problem formulation for TCE, particularly in relation to the following – • EPA has appropriately defined the conditions of use for the risk evaluation to include those uses addressed in the 2014 assessment and to exclude potential exposure pathways for which long-standing regulatory and analytical processes already exist under other statutes administered by the Agency (Section 2.5); and • Previous Agency assessments of TCE have not incorporated a systematic review approach to evaluate studies; a reevaluation of the key studies identified by these previous assessments, more recent information relating to health endpoints reported by these studies, and available mechanistic data is critical to a robust analysis of human health hazards associated with TCE. This is particularly important in relation to the assessment of fetal cardiac malformations.

141	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, Exposure

N/A

1.0 Introduction The Chemical Products and Technology Division of the American Chemistry Council (ACC/CPTD) appreciates the opportunity to submit comments on the Office of Pollution Prevention and Toxics (OPPT) Problem Formulation of the Risk Evaluation for Trichloroethylene (TCE) (the Problem Formulation) under the amended Toxic Substances Control Act (TSCA). As described in the Problem Formulation, the purpose of the document is to outline the approach for analyzing and characterizing the potential risk from exposure to TCE uses. ACC/CPTD appreciates the focus that the Environmental Protection Agency (EPA) has brought to this process in such a limited time period. In particular, and as described below, ACC/CPTD supports EPA's approach to include all current conditions of use in the risk evaluation, while excluding historic ("legacy") uses and applications with existing regulatory frameworks under other EPA statutes. This will allow OPPT to focus its assessment of risks associated with exposure to TCE in an efficient and effective manner. It will further allow OPPT to avoid the potential for conflict with EPA's long standing approaches to addressing TCE under its other statutory authorities. It is critical that the Problem Formulation follow a clear and transparent approach to identifying and assessing the available hazard and exposure data, such as that outlined in the OPPT Systematic Review Principles. This is necessary to ensure transparency and compliance with the requirements of TSCA Section 26.

142	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, Policy, Human Health

2.4.2

As noted in the Problem Formulation, existing health assessments of TCE conducted by EPA – including the 2011 Integrated Risk Information System (IRIS) assessment conducted by the National Center for Environmental Assessment (NCEA) and OPPT's own 2014 assessment under the Work Plan Chemicals program – do not comply with the requirements for the use of the best available science and weight of scientific evidence (WOE) under TSCA §26 and as defined in OPPT's risk evaluation procedures. In particular, the previous EPA assessments fail to adequately apply the weight of evidence when evaluating non-cancer health endpoints associated with TCE exposure, including fetal cardiac malformations (FCM). In evaluating the potential developmental toxicity of TCE under TSCA, OPPT is required to conduct an independent, systematic review of the available information for TCE, including FCM, as outlined in the risk evaluation rule. Prior assessments for TCE that evaluated FCM should not be relied on as part of this risk evaluation process. As the Problem Formulation suggests, significant new information on cardiac defects has become available since the IRIS and Work Plan reviews and ACC/CPTD anticipates that further information will be available in time for the OPPT risk evaluation.6

Footnote:

6 The Halogenated Solvents Industry Alliance (HSIA) has initiated a drinking water study of the effects of TCE on fetal heart development in rats that is expected to be completed in time for inclusion in the OPPT risk evaluation.

143	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, Policy

2.2

2.0 OPPT has Appropriately Defined the Conditions of Use for Risk Evaluation

ACC/CPTD supports EPA's approach to include current conditions of use in the risk evaluation, while excluding historic ("legacy") uses and applications with existing regulatory frameworks under other EPA statutes. We support OPPT's decision to include the degreasing and spot cleaning uses of TCE in the current risk evaluation and to exclude consideration of potential exposures that are addressed under other statutes administered by EPA. As noted, OPPT conducted assessments of TCE use in degreasing and spot cleaning in 2014 as part of its Work Plan assessment program. These assessments, however, were not conducted according to the scientific standards specified in Section 26 of TSCA, as amended by the Lautenberg Chemical Safety Act (LCSA) passed in June 2016, and should not form the basis for the current evaluation. While the amended TSCA provides for finalization of rulemakings based on assessments completed prior to passage of the amendments, finalizing rules based on the 2014 assessments could prejudice any subsequent assessment of TCE or create inconsistency in OPPT's approach to considering the chemical. We acknowledge that OPPT may decide to proceed with rulemakings for degreasing and spot cleaning, but such rulemakings should be based on an updated risk evaluation conducted in compliance with TSCA Section 26.

145	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, RegNex

2.3

OPPT's decision to exclude potential exposures addressed under other statutes administered by EPA represents an inherently practical conclusion and one that is wholly consistent with the statute. From a practical standpoint, requiring OPPT to repeat evaluations of exposure pathways conducted under other EPA-administered statutes as part of a TSCA risk evaluation would be time-consuming and non-productive and likely cause OPPT to miss the 3-year deadline provided by the statute for completion of the evaluation. As for statutory compliance, Section 9 of TSCA instructs the Administrator to coordinate actions under the Act with those taken under other Federal laws administered by the Agency. It further provides EPA with the discretion to use these other laws – in lieu of TCSA - to address risks to health or the environment. In the Problem Formulation, OPPT indicates that it worked closely with EPA offices responsible for assessing and managing exposures under other statutes administered by EPA. As a result of this interaction, OPPT concluded that the Agency has ongoing programs to address TCE exposures from ambient air, ambient water, drinking water, disposal, sediment, and soil under the Clean Air Act, Clean Water Act, Safe Drinking Water Act, and Resource Conservation and Recovery Act, respectively. Consistent with the authority granted under Section 9, ACC supports the exclusion of these potential exposure pathways from the risk evaluation under TSCA.

146	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, Policy
147	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Exposure

2.2
2.3, 2.6

EPA also has indicated its decision to exclude "legacy" uses and disposal 9 from risk evaluations under TSCA on the basis that Section 6 focuses on "prospective, ongoing uses" of the substance. The EPA rulemaking further notes that TSCA does not provide the OPPT with an effective tool to address risks found to arise from uses (and exposures) for which there is no ongoing commercial manufacture, processing, or distributing. EPA correctly concludes, moreover, that "absent clear intent from Congress, courts will not hold a statute to be retroactive, or uphold an agency regulation that seeks to have such an effect." In light of the fact that potential exposures from legacy disposal of TCE are actively being addressed under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), ACC/CPTD agrees that there is no need to consider such exposures as part of the risk evaluation. Footnote: 9 In the risk evaluation rulemaking, EPA defines legacy disposal as disposals that have already occurred (e.g., a chemical substance currently in a landfill or in groundwater.) 82 Fed. Reg. at 33729.
3.0 OPPT Should Clarify How It Will Consider Worker Exposures as Part of the Risk Evaluation In the Problem Formulation OPPT has identified occupational exposures to TCE, but has not explained how it plans to assess exposures to workers or what risk management approaches might arise from the evaluation. ACC has submitted more detailed comments on the exposure assessments to be conducted as part of the risk evaluations, but ACC/CPTD wishes to emphasize some specific points relative to evaluating occupational risks. We are concerned about the suggestion on page 58 that OPPT use release data from the Toxic Release Inventory (TRI) or National Emissions Inventory (NEI) to estimate occupational exposure. Although TRI and NEI data are useful for assessing potential ambient air exposures to a substance, they can provide no insight into exposures in the workplace. To the extent that exposure data is lacking for a particular condition of use, EPA should engage the affected industries to provide such data and only consider TRI and NEI data as a last resort.

148	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, Policy
149	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General
150	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, Human Health

N/A
N/A
N/A

Section 9 of TSCA outlines a process for coordinating with the Occupational Safety and Health Administration (OSHA) and other federal agencies in the implementation of any risk management activities arising from the risk evaluation. The Problem Formulation describes OPPT's interactions with other EPA offices, but is silent on any discussions it has had with OSHA. In light of the significant differences in the criteria used by the two agencies in assessing potential risks, it is critically important that stakeholders understand how OPPT plans to coordinate its authority with that of OSHA.
4.0 Existing Assessments of TCE Are Not Consistent with OPPT's Systematic Review Principles or Section 26 of TSCA With respect to TCE, we are further encouraged that the Problem Formulation describes how aspects of the systematic review guidance will be applied. In particular, relevant studies will be evaluated using the data quality criteria for endpoints of interest, including immunotoxicity and reproductive and developmental toxicity. As discussed earlier, the TCE reviews conducted for IRIS in 2011 and for the Work Plan in 2014 did not include a systematic review approach (i.e., an approach that included critical appraisal of individual studies) to evaluating the available data for FCM effects and cannot be considered to be WOE reviews as defined by the risk evaluation rule and as required by Section 26 of TSCA.
5.0 Systematic Review of the Key Study Suggesting Cardiac Effects Likely Will Disqualify It from Further Consideration Given that the Problem Formulation references the previous IRIS and OPPT assessments that identify FCMs as the most sensitive health endpoint, it is important to acknowledge and address the controversy surrounding the cardiac data. The systematic review process described by OPPT, and in particular the process for evaluation of data quality for key studies via the criteria in the Application of Systematic Review in TSCA Risk Evaluations, should provide a platform for objectively evaluating the reliability of the FCM data – as well as other data that EPA will assess, including immune and cancer endpoints.

151	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health
152	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health

2.4.2
2.4.2

The Problem Formulation further indicates a heavy reliance on previously compiled and systematically reviewed data for characterization of human health endpoints. As discussed above, the human health data for TCE have not been subject to systematic review by EPA. Systematic review implies a specific process – it is not synonymous with reviewing information systematically or simply conducting a systematic literature search. Thus, in conducting the TSCA risk evaluation, it is important to recognize that while a 2016 update of available human, animal, and mechanistic data by EPA staff represents a good compilation of the available cardiac data, it falls well short of the systematic review approach described in the OPPT guidelines. Of particular concern is the failure of the 2016 analysis by Makris et al. to conduct a critical appraisal of validity of individual studies. Under OPPT guidelines, the evaluation of study quality directs that those with well documented flaws are eliminated from further consideration. Regarding the key study reporting FHM in laboratory animals by Johnson et al. (2016), Makris et al. identify several serious flaws that would disqualify the study from further consideration under the OPPT guidelines, including – • Test Design: Not all control groups were run concurrently with the exposure groups; control data from metabolite studies conducted from 1992-1994 were combined with study data from 1994-95 and gestation-only data from 1989-1993; • Exposure Characterization: Information on the preparation of the test substance was not reported; as indicated by the information submitted to this docket by the Halogenated Solvents Industry Alliance (HSIA), significant loss of TCE from drinking water samples can occur during sample preparation unless steps are taken to ensure the integrity of the samples; • Exposure Characterization: The reported exposure data could not be validated for some of the exposure groups; the earlier studies included in the Johnson et al. analysis used tap water of unknown composition in preparing samples for the studies conducted in the early 1990s; and • Data Presentation & Analysis: The statistical methods used were not appropriate; the authors calculated per-litter statistics by adding the total number of litters with at least one cardiac defect by the total number of litters rather than examining the proportion of pups per litter as recommended by EPA.
Despite these serious design and reporting limitations, and the inability of other laboratories to duplicate the results, Makris et al. conclude that "on the whole" Johnson et al. is considered suitable for use deriving toxicity values. However, the Makris et al. reassessment of the TCE-FCM database lacks key elements required for a transparent systematic review, including protocol development and a failure to include a risk-of-bias assessment.

153	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health
154	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health
155	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health

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In addition to the issues identified by Makris et al., study design shortcomings that would otherwise lead to rating the Johnson et al. study as low quality include – • Non-concurrent dose groups: The comparison of data sets from TCE exposure groups that were not tested concurrently (i.e., high-dose groups reported in an earlier study with low-dose groups later reported in Johnson et al.); • Ad hoc pooling of control data: Data from unexposed "control groups" that were used in different experiments at different times across a 6-year period were pooled and used as the basis of comparison with TCE exposure groups; and • Unconventional dose spacing: The difference between the highest and lowest in TCE dose groups was nearly six orders of magnitude.
More recently, Wikoff et al. (2018) conducted a risk-of-bias analysis of the heart defects data for TCE that more closely aligns with many of the elements of the OPPT systematic review guidance. Such an evaluation of the risk of bias is a critical element of any systematic review. Using the National Toxicology Program's tool, the authors conclude that the study by Johnson et al. had the highest risk of bias of all of the animal studies in the evidence base. As a result of the high risk of bias, inconsistent findings with all other animal studies with lower bias ratings, and the inability to replicate study findings, the authors conclude that "the Johnson et al. study is not sufficiently reliable for hazard characterization or development of noncancer toxicity values."
In evaluating the human studies, moreover, Wikoff et al. conclude that "there are no data of sufficient quality" to develop conclusions regarding the potential for health effects. This conclusion is consistent with that reached by Bukowski (2014) as well as Makris et al. Of the nine human studies included in all three reviews, only three provide evidence for an association with FCM. All three of these studies lack accurate exposure information and fail to adequately control for potential confounding factors. Among the negative studies, are investigations of large, high-profile populations in Woburn, MA and Camp Lejeune, NC over extended periods of time (greater than 20 years), as well as a study in New Jersey that included the largest birth population of any of the studies assessed.

156	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health
157	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health, Eco Health
158	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health, Eco Health

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Based on the risk of bias and data integration findings from animal and human studies, Wikoff et al. concluded that FCM are not a suitable end point upon which to base a quantitative assessment. This is in agreement with conclusions reached in an earlier European occupational exposure assessment of the TCE-FCM database – • Epidemiological evidence does not support the occurrence of this teratogenic effect after human uptake of TCE from contaminated drinking water, and animal studies demonstrate such effects at much higher doses than those relevant for [occupational exposure level] derivation . . . In addition, positive results are contradicted by qualified negative studies . . . An overall evidence for development of congenital heart disease due to TCE exposure in relevant doses is not sufficiently supported.
In addition to the animal and human studies, Makris et al. pointed to a number of in vitro and in ovo (avian) studies to support their conclusion that the Johnson et al. study is adequate for quantitatively assessing TCE risk. As with the other data, the EPA scientists did not subject the mechanistic data to a systematic review. Importantly, there are notable shortcomings in both the design and relevance of these studies. These limitations include – • the use of TCE exposure levels in in vitro studies that are orders of magnitude higher than exposures reported in the animal and human studies; and • critical differences in the avian vs. mammalian models, including differences in exposure duration, the irrelevant exposure route, and the lack of both maternal influence and placenta.
The relevance of the reported in vitro and avian studies to human health is highly questionable. The uncertainties of extrapolating dose levels from in ovo study results to mammals and humans are considerable, making these studies not directly applicable to human health risk assessment. In addition, in discussing a potential mechanism of action for cardiac effects, Makris et al. link the findings from 32 studies without assessing whether the studies are equally relevant and the results valid in constructing the proposed mechanism.

159	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health, Eco Health
160	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health
161	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, Human Health
162	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, Human Health

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N/A
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A more recent study published by Harris et al. (2018) reported on the in vitro and in ovo effects of TCE on the expression of the transcription factor HNF4a (Hepatocyte Nuclear Factor 4 alpha). Harris et al. suggest that HNF4a is a key protein involved in cardiac development. However, the study design is limited and inadequate for extrapolating the findings to humans and the results are poorly reported (e.g., errors in labeling, inadequate information regarding the statistical significance of the findings). The functional endpoint examined in this study (i.e., cardiac contraction) in particular is especially unpersuasive as the controls demonstrated considerable method variability.
Makris et al. suggest that the mechanistic data is sufficient for developing a “preliminary conceptual model of an adverse outcome pathway (AOP) for valvulo-septal defects resulting from TCE exposures.” This is a key assertion used by these authors to support their argument that the mechanistic data “supports the biological plausibility of an effect on cardiac development with exposure to TCE.” However, an AOP describing the complete process from initial biomolecular perturbations to the various and diverse types of cardiac malformations that were reported in the TCE-exposed rats in the Johnson et al. study has not been proposed to date. This highlights the important data gaps in the current knowledge base, further calling into question the plausibility of the TCE-FCM hypothesis.
With this in mind, EPA/OPPT should evaluate the TCE-FCM mechanistic literature in a systematic fashion, including via the application of clear and objective study quality metrics that will allow for a comprehensive assessment of the quality of this database.
Taken together, the available lines of evidence (i.e., animal, human, and mechanistic) do not support the use of the Johnson et al. study to develop toxicity values for TCE. OPPT should eliminate the use of the Johnson et al. study in its risk assessment as it does not meet the minimum necessary quality standards.

163	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, Human Health, Eco Health
164	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health
165	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health

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6.0 Elimination of the Johnson et al. Study is Supported by the Lack of Evidence in Other Laboratory Analyses

TCE has only been associated with cardiac defects in animal studies conducted at the University of Arizona laboratory. The first report from the Arizona lab was based on the injection of very high concentrations of TCE directly into the fertilized chick eggs which are of questionable relevance to humans. Subsequent studies from the laboratory in which TCE was administered to rats in drinking water produced anomalous dose-response results achieved through non-conventional statistical analysis. Johnson et al. reported that TCE produces cardiac teratogenicity and no other adverse developmental effects. No other laboratory has been able to reproduce these results.

In several well-designed and conducted studies using standard techniques for identifying developmental hazards, rats, mice, and rabbits were exposed to TCE by inhalation at doses as high as 600 ppm (Carney et al. 2006) and rats were exposed by oral gavage to 500 mg/kg/day of TCE (Fisher et al. 2001). Neither of these studies reported exposure related developmental toxicity, even in the presence of maternal toxicity. Furthermore, neither reported significant evidence of specific cardiac teratogenicity.

Importantly, these two studies used the highest TCE exposure concentrations and are not limited by the study design and reporting flaws that underlie the Johnson et al. study. Further, the Fisher et al. developmental toxicity study was explicitly designed to replicate the high-dose TCE-FCM reported in Johnson et al. The investigators even enlisted the help of Dr. Paula Johnson, the lead scientist of the Johnson et al. study, for her expertise on the fetal heart dissection and evaluation technique used by the University of Arizona laboratory. Despite these efforts, Fisher et al. were unable to reproduce the FCM reported in the Johnson et al. study.

166	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health
167	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health

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While the Fisher et al. study was conceived as a hazard identification study, and therefore had some study design differences relative to Johnson et al.,40 the authors reported no statistical difference in FCM incidence in the fetuses from vehicle control and TCE-treated dams. The Fisher et al. study was of higher quality in design and reporting relative to Johnson et al., included concurrent controls, included a positive control (retinoic acid) that demonstrated the efficacy of the FCM evaluation technique, and reported appropriate per-litter statistics. Although several possible explanations for the differences in the results reported in the two studies have been suggested, the most likely is the use of non-traditional statistical analysis – first in the use of per-fetus, rather than per-litter, results and subsequently in the use of pooled, non-concurrent control groups as the basis for comparison. Footnote: 40 For example, TCE was administered via daily oral gavage in the study by Fisher et al. instead of via drinking water and the pregnant rats were exposed during the primary period of organogenesis (gestation days 6–15) instead of throughout gestation.
A subsequent study by Carney et al. was designed to determine if inhalation exposures would result in FCMs. This was a high-quality experimental animal study designed and performed according to GLP protocols set forth in EPA and Organisation for Economic Co-Operation and Development (OECD) guidelines for developmental toxicity testing (OPPTS 870.3700; OECD Guideline 414). The authors reported no significant increase in FCMs, despite TCE concentrations ranging from 125,000- to 1,500,000-fold higher than the EPA IRIS reference values, which are in part based on route-to-route extrapolation of FCM data from the Johnson et al. study.

168	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health
169	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health
170	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Other

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N/A

As a result of the concerns about the data reported by Johnson et al., California's Office of Environmental Health Hazard Assessment (OEHHA) concluded that – "[t]he data for this [Johnson et al.] study were not used to calculate a public-health protective concentration since a meaningful or interpretable dose-response relationship was not observed. These results are also not consistent with earlier developmental and reproductive toxicological studies done outside this lab in mice, rats, and rabbits: The other studies did not find adverse effects on fertility or embryonic development, aside from those associated with maternal toxicity."
Similarly, in evaluating the TCE science, the NRC (2006) noted that the "low-dose studies showing a positive correlation in TCE-induced cardiac teratogenesis showed unusually flat dose-response curves and came from a single laboratory. The results need to be replicated in another laboratory to clarify the dose-response relationship. As indicated previously, no lab has been able to replicate the results reported by Johnson et al. As of now, the inhalation study conducted by Carney et al. represents the most recent experimental animal study designed to examine potential TCE-FCM and also reflects the relevant route of exposure for development of inhalation toxicity values.
7.0 OPPT's Literature Search is Lacking Two Key Studies The 2017 Scoping Document and 2018 Problem Formulation for TCE include the literature search and screening strategies developed by OPPT, as well as the initial results of these activities. OPPT notes that the TSCA systematic review strategy the Office plans to use for the risk evaluation of the first ten chemicals will be iteratively developed as it carries out the risk evaluations for these initial chemicals. Thus, OPPT states in the 2017 TCE Bibliography (supplemental file): "Additional on topic references not initially identified in the initial search may also be identified as the systematic review process proceeds." However, the Problem Formulation indicates that key studies will be identified based on secondary sources (e.g., ATSDR Toxicological Profile and previous EPA assessments) along with a literature search as presented in the supplemental file. It is not clear if an additional literature search for TCE will be conducted beyond that already described in the Problem Formulation.

171	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health
172	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	Human Health
173	EPA-HQ-OPPT-2016-0737-DRAFT-0117_ACC-CPTD	1	General, Human Health
174	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	General

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N/A
N/A

The following publications should be included in the risk evaluation for TCE – • Beliles et al. (1980): This is the publicly available technical laboratory report that supplements Hardin et al. (1981). Hardin et al. (1981) is a general summary of a series of teratogenicity studies that includes TCE inhalation experiments in pregnant rats and rabbits. The experiments were conducted by a contract research laboratory (Litton Bionetics) on behalf of the National Institute for Occupational Safety and Health (NIOSH), and the technical details of these experiments are reported in the Beliles et al. (1980) report. • Wikoff et al. (2018): A risk-of-bias evaluation of the animal and human studies used as the basis for the IRIS and Makris et al. assessment of the association between TCE and FCM. The authors used the OHAT 2015 risk-of-bias tool to evaluate data quality of the relevant literature.
The former report is important for evaluating the data quality of the Hardin et al. paper, and the latter is the only example in the literature of a systematic evaluation of risk of bias and subsequent integration of TCE-FCM literature using readily accepted systematic review methods. OPPT should include these as "on-topic" references in the "Human Health Hazard Literature" and "OPPT Risk Assessment" categories of the OPPT TCE literature database.
For TCE specifically, Wikoff et al. address the differentiation of internal and external validity as it relates to evaluating and integrating evidence from animal studies and human studies.
Thank you for the opportunity to provide comments on the problem formulation document for trichloroethylene (TCE). Silent Spring is a non-profit research organization that focuses on understanding the toxicity of and exposure to chemicals that may increase the risk of breast cancer. Breast cancer is the most common form of cancer in American women, and a leading cause of death from cancer in women. Our research is focused on identifying environmental risk factors because no one should have an increased risk of breast cancer from exposure to chemicals.

175	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Exposure
176	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Exposure
177	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Exposure

2.2.2.1
2.2.2.1
2.3.2

Conditions of Use (Section 2.2.2.1) We applaud the EPA's decision to include conditions of use identified in EPA's 2017 Scope of the Risk Evaluation for Trichloroethylene, including use as an intermediate or reactant, lubricant, or adhesive, and use as an ingredient in consumer products (EPA 2017). We are also encouraged to see the EPA include uses previously assessed in EPA's 2014 risk assessment (solvent degreaser, spotting agent, and protective coating for arts and crafts) (EPA 2014). These inclusions will help EPA come to a more accurate evaluation of any unreasonable risk posed by TCE, especially from cumulative exposures. However, since TSCA section 26(l)(4) explicitly allows rulemaking on the bases of uses included in the 2014 Work Plan assessments and EPA has already begun to issue risk determinations and rules on that basis, EPA should not subject uses and exposures undergoing rulemaking to re-evaluation. Instead, EPA should incorporate its existing data and conclusions and focus on evaluating uses and exposures that have not undergone rulemaking.
The basis for excluding consumer paints and coatings from evaluation is unclear. The EPA is excluding evaluation of TCE in paints and coatings for consumer use based on EPA's 2016 significant new use rule (SNUR), which reports that TCE is not expected to be present in consumer products other than cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, and pepper spray (EPA 2016). However, the 2016 SNUR relies on analyses performed for the 2014 TCE Work Plan Chemical Risk Assessment, which offers little supporting information. In addition, several other consumer products such as hair and wig glues and gun scrubbers were retained in the conditions of use (Table 2-3). A more comprehensive and detailed accounting of the use or non-use of TCE in consumer products should be included in the draft risk evaluation to justify the exclusion of any conditions of use.
Releases to the Environment (Section 2.3.2) The total amount of TCE used in consumer products should be calculated and considered to be released to the environment. This TCE volume will end up in the air or groundwater during use or from waste disposal.

178	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Exposure
179	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	PESS

2.3.5.1
2.3.5.4, 2.4.2.4

Occupational Exposures (Section 2.3.5.1) Under Inhalation, the EPA summarizes regulatory and non-regulatory exposure limits for TCE. It would be appropriate to include the EPA RfC (estimated concentration likely to be without significant risk of harmful effects) for continuous TCE exposure (0.002 mg/m3) in this section. The state of Massachusetts uses this number to derive an occupational guideline of 0.08 mg/m3 (Mass DEP 2014).
Potentially Exposed or Susceptible (Section 2.3.5.4 or Section 2.4.2.4) We suggest including additional populations in EPA's evaluation of risk to highly exposed or susceptible populations. Individuals highly exposed to TCE through past environmental contamination (such as TCE from a subsurface groundwater plume entering a home) should be included on the basis of exposure. These exposures should also be evaluated in combination with exposures from current conditions of use and associated environmental releases. We also direct EPA's attention to the use of TCE in hair extension and lace wig glue. Use of these products may be of particular concern for Black women, who disproportionately suffer from health and environmental justice disparities. There are also groups of individuals who may be more biologically susceptible to the hazards associate with TCE. Individuals with alterations in the CyP2E1 enzyme may have different exposure patterns to TCE or its metabolites (EPA 2011). EPA removed a reference to this possible source of susceptibility that was present in the previous scoping document, and we urge its inclusion in the draft evaluation. Finally, because of TCE's developmental toxicity, EPA must explicitly name pregnant women and fetuses as susceptible populations for occupational, consumer, and general population exposures.

180	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Human Health
181	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Exposure

2.4.2
2.5.3.3

Human Health Hazards (Section 2.4.2) We support the inclusion of fetal cardiac malformations as the most sensitive endpoint under reproductive/developmental effects. We were pleased to see that EPA retained language supporting the use of animal cancer data to infer human cancer hazard for this evaluation. Finally, we remind EPA of the epidemiological evidence linking breast cancer with TCE exposure. An Italian study of electrical manufacturers found increased odds of breast cancer among women who had ever worked with TCE compared to women with “blue collar” job titles at the plant who had never worked with TCE, and those odds increased when further limited to women who had worked at the factory for more than 10 years (Oddone, Edefonti et al. 2014). Additional epidemiological studies have found positive associations with breast cancer and occupational exposure to TCE (Sung, Chen et al. 2007; Radican, Blair et al. 2008).
Pathways that EPA Does Not Plan to Include in the Risk Evaluation (Section 2.5.3.3) The EPA does not plan to include exposures to the general population or environment arising from release of TCE to air, water, groundwater, or land (including landfills), on the basis that these releases are already adequately assessed and managed by existing environmental statutes. However, existing environmental statutes cannot substitute for evaluation of the risk from these releases in this risk evaluation for three major reasons. First, not all TCE releases are assessed or controlled under these programs. Second, relevant regulations take into account cost and other factors that TSCA cannot legally consider in this portion of the evaluation. Third, the residual risk remaining in the presence of existing regulations has not been comprehensively assessed.

182	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Exposure
183	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Exposure
184	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Exposure

2.5.3.3
2.5.3.3
2.3, 2.5, 2.6

The following are some of the many gaps in TCE management under existing statutes. The EPA cites the Clean Air Act Hazardous Air Pollutant (HAP) as effectively covering emissions to air from stationary sources and Safe Drinking Water Act standards as effectively addressing exposures in drinking water. However, HAP rules are applied on a source by source basis and regulations only exist for some sources. Where regulations do exist, the regulations are often outdated: the most recent Risk Technology Review for Halogenated Solvent Cleaning dates to 2007 (EPA (Environmental Protection Agency) 2007), while a newer review should have been issued in 2015. HAP regulations are also based on cost and energy considerations that are not permitted in TSCA risk evaluations. The National Primary Drinking Water Regulations under the Safe Drinking Water Act cover public water sources, not private wells. For consumer products, very few regulations limit release to the environment.
We strongly encourage the EPA to comprehensively assess all environmental emissions identifying each source, the relevant regulation and resulting reduction in emissions, and estimating residual exposure to the general population and the environment. Importantly, EPA must estimate the total residual exposure in each context separately (for example to the general population from the air, from drinking water, from ground water/subsurface vapor) and in combination from all sources.
Aggregate and cumulative exposures In its response to comments, EPA states that it will consider whether to address aggregate exposure in the next, analysis phase, and has not yet decided whether to assess risk from cumulative exposures. We urge EPA to include both aggregate and cumulative exposure assessments in the risk evaluation.

185	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Exposure
186	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Exposure

2.3
2.3

In order to ensure that exposure models and assessments adequately capture, and do not underestimate, exposure, we encourage the EPA to consider aggregate exposures in the following ways: • Consider combined exposures across different routes of exposure (inhalation, oral, dermal) for each population: occupational, consumer, and general. • Calculate an aggregate exposure of consumer exposures that also account for the exposures that individuals encounter as members of the general population. • Calculate an aggregate exposure of occupational exposures that also account for exposures that workers or occupational non-users encounter outside the workplace, as consumers and members of the general population. • General population exposures must include current exposures to TCE from past releases to the environment.
Because exposure to TCE co-occurs with other related chemicals, cumulative effects from coexposures to chemicals that act in similar ways should be considered. An investigation of Marines stationed at Camp Lejeune, North Carolina found that the Camp's population was exposed to TCE in drinking water, as well as perchloroethylene (PCE), benzene, and vinyl chloride (Ruckart, Bove et al. 2015). Co-exposure to chemicals that have similar toxic action may act in a dose additive manner. An example of chemicals with similar modes of action considered for dose additive effects and cumulative exposures is phthalates. Concurrent exposures to some phthalates result in a greater effect than exposure to individual phthalates (National Research Council 2008). The Consumer Product Safety Commission prohibits childcare products from containing a group of phthalates that have anti-androgenic activity for their cumulative exposures and effects on the male reproductive system (U.S. Consumer Product Safety Commission 2014). We encourage EPA to investigate toxic activity exhibited by TCE that overlaps with similar activity exhibited by related chemicals with potential co-exposures in order to assess the need for a cumulative risk assessment.

187	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Exposure
188	EPA-HQ-OPPT-2016-0737-DRAFT-0118_Silent-Spring-Institute	1	Exposure
189			

2.3
2.3

Upper bound exposures We encourage the EPA to consider the maximum or 99th percentile when calculating risk. Maximum values can skew considerably higher than the median or 95th percentile. If an exposure scenario is chosen that doesn't account for the most exposed individuals, many individuals could be left unprotected from TCE's effects. We thank EPA for its attention to these issues, and look forward to reviewing them further in the draft risk evaluation.

Upper bound exposures We encourage the EPA to consider the maximum or 99th percentile when calculating risk. Maximum values can skew considerably higher than the median or 95th percentile. If an exposure scenario is chosen that doesn't account for the most exposed individuals, many individuals could be left unprotected from TCE's effects. We thank EPA for its attention to these issues, and look forward to reviewing them further in the draft risk evaluation.

Problem Formulation Documents - Public Comments

ASBESTOS SPECIFIC COMMENTS

#	Submitter	Attachments (#)	Category	Document Section #
1	EPN_CommentJuly312018	1	RegNex	N/A
2	EPN_CommentJuly312018	1	Exposure, RegNex, Policy	N/A

Comment
The Environmental Protection Network (EPN) is providing the following comments on the problem formulations for asbestos, HBCD and carbon tetrachloride, which we find are setting improper precedents for future chemical risk evaluations under the new Chemical Safety Act amendment to TSCA. The final rule states that EPA is given discretion to determine the conditions of use that it will address in its evaluation of a priority chemical, "in order to ensure the agency's focus is on the conditions of use that raise the greatest potential for risk." The final rule mentions excluding de minimis conditions of use or conditions of use that have been adequately addressed by another regulatory agency. The final rule also states that while the statute is ambiguous as to whether the conditions of use should include legacy uses, "in a particular risk evaluation, EPA may consider background exposures from legacy use, associated disposal and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses."
In the following sections of our public comments, the Environmental Protection Network will explain: 1) why the asbestos and HBCD problem formulations should not exclude pathways of exposure to legacy uses; 2) why the asbestos problem formulation should not exclude pathways of exposure regulated under other programs; 3) why the carbon tetrachloride problem formulation should either evaluate the conditions of use now designated as "de minimis" or provide a science-based justification for their exclusion and rationale for not seeking additional information from industry; and 4) why EPA needs to take the lead in addressing workplace risks while consulting with OSHA.

RAD POC	Docket #	Action Needed

3	EPN_CommentJuly312018	1	Exposure, Policy	N/A
4	EPN_CommentJuly312018	1	Exposure, Human Health, Policy	N/A

1. EPA's Proposed Approach to Risk Evaluation of Exposures Related to Legacy Use is Flawed. The exclusion of "legacy" exposures in the problem formulation documents is particularly flawed for asbestos, and very likely problematic for the cyclic aliphatic bromide cluster chemicals (HBCD) as well. While much of the current risks from asbestos occur among workers involved in asbestos abatement or removal during remodeling, demolition and disposal, there are also risks among maintenance workers with in-place asbestos and auto mechanics performing brake work. Reports published by CDC and IARC strongly suggest that these uses contribute to the widespread release of fibers into the general environment, even with adherence to OSHA and other regulatory limits.
It is well documented that asbestos is a carcinogenic compound. There is no safe level of exposure. The ATSDR noted that asbestos is a dangerous substance and should be avoided. Risk is dependent on frequency and duration of exposure. Breathing asbestos can cause asbestosis, lung cancer and mesothelioma. This was the finding reported in the EPA peer-reviewed report on the destruction of the World Trade Center. This report stated that the continuing release of asbestos fibers posed a serious hazard to humans unknowingly exposed to residual fibers and would continue to do so for a long period of time. Exposure risks were also addressed in an EPA 2004 pamphlet describing risks from release of asbestos fibers from brake pads. In the pamphlet, EPA stated that asbestos exposures during daily work on brakes and during the disposal of asbestos-containing products are a serious concern for the mechanics and other workers within the facility. In addition, asbestos is described in the problem formulation document as primarily a respiratory disease hazard (asbestosis, lung cancer and mesothelioma), but there is strong evidence to suggest that asbestos also poses a risk of stomach, larynx, pharynx and possibly reproductive system cancers. These risks are dismissed in the problem formulation document without explanation. They should be part of the comprehensive risk assessment. Knowing that everyone is exposed to some level of background asbestos exposure is not a reason to ignore the hazards that remain from legacy exposures such as the removal of in-place asbestos materials, and the exposure of populations who live near former mines that have produced contaminated living environments. It would be a reckless decision to ignore the long-term exposures that still occur from legacy pathways and their resultant health hazards. A recent example of asbestos exposure occurred in Manhattan when a steam pipe lined with asbestos exploded on July 19, 2018 (New York Times , July 19, 2018).

5	EPN_CommentJuly312018	1	RegNex	N/A
6	EPN_CommentJuly312018	1	Exposure, RegNex	N/A
7	EPN_CommentJuly312018	1	RegNex	N/A

We have focused our comments on this issue in the asbestos problem formulation as an example case. All of our objections and concerns about this approach for asbestos would apply to the other nine chemicals, and depending on specifics, the use of this approach for those chemicals would likely raise additional concerns as well.
In the case of asbestos, the combination of determining that "legacy uses" are not conditions of use and of omitting disposal because of RCRA regulation has the effect of omitting entirely consideration of disposal, which is specifically enumerated in the statutory definition of conditions of use.
Below are two examples from the asbestos problem formulation document that illustrate how legally insufficient the alternative programs can be for this purpose. Congress intended for TSCA to have a risk-based standard and to use this standard to evaluate high priority chemicals that had never been evaluated under other programs based only on risk. Asbestos air quality regulation dates back to 1986 and is based on an older version of the Clean Air Act (CAA), which did not require consideration of residual risk or all possible exposure pathways. Even if the existing asbestos regulation had been based on the current CAA, it would not be consistent with TSCA's sole focus on health effects. The framework for regulation of hazardous air pollutants under the current CAA is generally fundamentally different from the TSCA process. Hazardous air pollutants (HAPs) are regulated under the CAA in two stages. The first stage is based upon maximum achievable control technology (MACT) within each specific industry. Under MACT, EPA identifies the best performing technologies within an industry and sets a standard based on the performance of these technologies. The cost of achieving such emission reduction and any non-air quality health and environmental impacts and energy requirements, but not risk, are considered at this stage. The second phase of HAP control under the CAA is a "risk-based" approach in which the risk remaining after the application of MACT is assessed. Within eight years of setting the MACT standards, the CAA requires EPA to assess the remaining risks from each source category to determine whether the MACT standards protect public health with an ample margin of safety and protect against adverse environmental effects. While EPA does not have to consider the costs of any health standards imposed as a result of the risk analysis, it must consider the costs of a more stringent standard to reduce environmental risks. Furthermore, the residual risk controls only apply to major emission sources; they do not apply to small emitters considered as area sources.

8	EPN_CommentJuly312018	1	RegNex, Policy	N/A
9	EPN_CommentJuly312018	1	RegNex, Policy	N/A
10	Healey_CommentAugust72018	1	General	N/A

EPA's own discussion of the asbestos requirements under the Resource Conservation and Recovery Act illustrates clearly the gaps between the regulatory approaches to asbestos under RCRA and those required by TSCA. Indeed, the problem formulation document itself makes clear that significant amounts of the considerable quantities of disposal (>25 million pounds) from the on-going asbestos uses are subject only to certain state-level requirements. [p. 44]
The amended TSCA contains new standards for assessment of chemicals, but also a host of new provisions to ensure open processes, fairness and other vital good government goals. The approaches to regulation of asbestos under other statutes generally not only have different substantive standards of review, but also different processes and procedures, especially for the risk assessment aspects of the regulatory process.
Massachusetts also comprehensively regulates asbestos through a set of overlapping state and delegated federal programs involving multiple state agencies. From 2011–2015, the U.S. Centers for Disease Control and Prevention (CDC) reports there were 441 new cases of mesothelioma in Massachusetts, resulting in 366 deaths. Asbestos exposure is the known cause of mesothelioma. •The Massachusetts Department of Environmental Protection ("MassDEP") is authorized by the Massachusetts Clean Air Act, M.G.L. c. 111, §§ 142A-O, and the federal Clean Air Act, 42 U.S.C. § 7401, et seq., to prevent air pollution by regulating asbestos handling, transport, and disposal. • MassDEP requires notice and remediation of releases of asbestos to the environment as a hazardous material under the state's "superfund" law, M.G.L. c. 21E. • MassDEP also regulates the disposal of asbestos under the Massachusetts Solid Waste Management Act, M.G.L. c. 111, § 150A. • The Massachusetts Department of Labor Standards ("DLS") ensures worker safety in Massachusetts by licensing asbestos-related work and requiring the use of proper work practices and safety equipment pursuant to M.G.L. c. 149. • DLS is also delegated authority under the Asbestos Hazard Emergency Response Act, 15 U.S.C. § 2641, et seq., to regulate asbestos in schools for the safety of the school community. • The Massachusetts Office of the Attorney General is empowered to initiate litigation to enforce these state statutes and to seek court orders for compliance and civil penalties. The Attorney General also conducts other work to encourage the safe use and public awareness of asbestos, such as leading a multi-party stakeholder effort to create a comprehensive online public database of asbestos information about Massachusetts schools in response to a report by the Office of Senator Edward J. Markey identifying a lack of this information nationally.

11	Healey_CommentAugust72018	1	Other, Policy	N/A
12	Healey_CommentAugust72018	1	Other, Policy	N/A
13	Healey_CommentAugust72018	1	Other, Policy	N/A

With the exception of HBCD and Pigment Violet 29, each of the Initial Ten TSCA Chemicals is listed as either a carcinogen and/or reproductive toxin under California's Safe Drinking Water and Toxic Enforcement Act of 1986 known as "Proposition 65."
The adverse impacts to California these substances cause are further demonstrated by the following: • From 2011–2015, the CDC reports there were 1,716 new cases of mesothelioma in California, resulting in 1,318 deaths. Asbestos exposure is the known cause of mesothelioma. • There have been at least two deaths in California caused by exposure to paint strippers containing methylene chloride since 2012. • There are 37 sites in California with TCE contamination that have been or are on the National Priorities List (NPL) under the Comprehensive Environment Response, Compensation and Liability Act (CERCLA), 29 with PCE contamination, 6 with asbestos contamination, 10 with 1,4-dioxane contamination, 36 with methylene chloride contamination, and 25 with carbon tetrachloride contamination. • In 2016, the most current Toxic Release Inventory (TRI) reporting year, a combined total of 2,124,369 pounds of 1,4-dioxane, asbestos, carbon tetrachloride, NMP, PCE and TCE was reported as having been disposed of or released in California.
Maine also comprehensively regulates asbestos abatement activities to ensure safe working conditions pursuant to its asbestos law, 38 M.R.S. §§ 1271-1284, and its corresponding rule, 06-096 CMR ch. 425, and the disposal and transportation of asbestos under its Solid Waste Management Rules, 06-096 CMR ch. 401 (disposal); 06-096 CMR ch. 411 (transportation). Additionally, in Maine, all sellers of residential real property are required to disclose the presence of asbestos or the prior removal of asbestos to potential buyers.39 From 2011–2015, the CDC reports there were 128 new cases of mesothelioma in Maine, resulting in 107 deaths. Moreover, the Maine Department of Environmental Protection has been delegated by the U.S. Environmental Protection Agency to conduct periodic Asbestos Hazard Emergency Response Act (AHERA) compliance inspections in Maine's non-profit school systems.

14	Healey_CommentAugust72018	1	Other, Policy	N/A
15	Healey_CommentAugust72018	1	Other, Policy	N/A
16	Healey_CommentAugust72018	1	Other, Policy	N/A

Maryland: Maryland regulates the manufacture, sale, use, and disposal of chemicals—including some of the substances to be addressed in EPA's initial risk evaluations—in a variety of ways. For instance, businesses engaged in the removal or encapsulation of asbestos may do so only pursuant to a license issued by the Maryland Department of the Environment—which, in turn, has prescribed strict procedures governing such activities. From 2011–2015, the CDC reports there were 258 new cases of mesothelioma in Maryland, resulting in 207 deaths.
As regards asbestos, New York has a number of regulatory programs in place: the Department of Health certifies and trains employees who perform asbestos abatement; the Department of Labor regulates asbestos abatement and removal projects; and the Department of Environmental Conservation regulates the transportation and disposal of asbestos waste.
Oregon: Oregon has adopted, and is considering, several state-specific statutes and regulations to manage the impacts of toxic and hazardous pollutants that encompass the majority of the Initial Ten TSCA Chemicals. These programs include: • Asbestos emissions, disposal, licensing and certification requirements. From 2011–2015, the CDC reports there were 245 new cases of mesothelioma in Oregon, resulting in 223 deaths. • Air toxics permits and benchmarks for industrial facilities. In addition, Oregon is currently in the process of developing new rules on industrial air emissions that would regulate emissions based on health risks to neighboring communities. The proposed rules will regulate emissions of hundreds of chemicals, including several of the Initial Ten TSCA Chemicals: asbestos, 1-bromopropane, carbon tetrachloride, 1,4 dioxane, tetrachloroethylene, and trichloroethylene. Oregon is relying on federal guidance and expertise to help define potential health risks for communities that are exposed to these emissions and to ensure that communities are protected from cumulative risks from other potential exposure pathways. • Toxics Use and Hazardous Waste Reduction planning requirements, which apply to large and small quantity generators of hazardous waste and Toxic Release Inventory reporters. • State cleanup and remedial actions for hazardous substances, and separate rules for dry cleaning facilities with perchloroethylene (tetrachloroethylene). In addition, legacy contamination from industrial sites is still a potential source of exposure to several of the Initial Ten TSCA Chemicals. The Oregon Health Authority's Environmental Health Assessment Program evaluates potential public health risks from contaminated sites across our state. In the last year alone, the program has been asked to evaluate public health risks from sites where environmental monitoring projects detected at least one of the Initial Ten TSCA Chemicals, including 1,4 dioxane, carbon tetrachloride, methylene chloride, tetrachloroethylene, and/or trichloroethylene. • Oregon adopted the Toxic Free Kids Act in 2015, requiring manufacturers of children's products to report the presence of specific chemicals of concern in products sold in Oregon. Several of the Initial Ten TSCA Chemicals are being reported in that program, including 1,4 dioxane, methylene chloride, tetrachloroethylene, and hexabromocyclododecane. Oregon relies on information from federal agencies to evaluate potential health risks of chemicals of concern for children, to identify new chemicals of concern to add to the reporting list, and to help address cumulative risks from these chemicals through other routes of exposure.

17	Healey_CommentAugust72018	1	Other/Policy	N/A
18	Healey_CommentAugust72018	1	Other, Policy	N/A
19	Healey_CommentAugust72018	1	Exposure	2.2

In the context of hazardous waste and toxics reduction, Washington State has additional statutes that authorize Ecology to regulate asbestos and many Initial Ten TSCA Chemicals due to their associated harms to public health and the environment. For example, Washington's Better Brakes Law mandates a phase out of asbestos in brake friction material that is sold, or offered for sale, in Washington State. From 2011–2015, the CDC reports there were 463 new cases of mesothelioma in Washington State, resulting in 394 deaths.
The District also regulates the removal and abatement of asbestos through its own licensing and permitting requirements to ensure the safe removal and disposal of asbestos-containing material and the safety of asbestos abatement workers and the surrounding community.
The most glaring and egregious example of this dereliction of EPA's statutory obligations comes in the Problem Formulation for asbestos. Asbestos is a known carcinogen and there is no safe level of exposure to this highly toxic material ubiquitous in our built environment. The potential for harm posed by asbestos is universally recognized and addressing its risks was a priority in reforming TSCA: "Asbestos, for example, is one of the most harmful chemicals known to humankind, and it takes 15,000 lives a year. It is linked to a deadly form of lung cancer called mesothelioma. People can breathe in these fibers deep into their lungs where they cause serious damage. We have addressed asbestos in this bill. We didn't ban it on this bill, which I support . . . but we have made asbestos a priority in this bill." EPA's failure to consider so-called "legacy" uses of asbestos (e.g., asbestos currently in place in buildings and on pipes and equipment) in its risk evaluation process, and the agency's failures otherwise to identify properly the conditions of use for asbestos, means EPA will not consider the risks from, among others, aging asbestos-containing tiles, adhesives, and piping in millions of homes, commercial buildings, and in underground infrastructure nationwide. 81 By failing to identify and assess exposures from the full range of known and likely uses, EPA is failing to characterize the full range of risks posed by asbestos and thus cannot possibly satisfy its mandate under TSCA to eliminate unreasonable risks of injury to health or the environment, without consideration of costs or other non-risk factors, including unreasonable risks to a potentially exposed or susceptible subpopulation. Footnote 81 Legacy uses of asbestos excluded from the scope of the risk evaluation include: asbestos arc chutes; asbestos packings; asbestos pipeline wrap; asbestos protective clothing; asbestos separators in fuel cells and batteries; asbestos-cement flat sheet: asbestos-cement pipe and fittings; asbestos-cement shingles; asbestos-reinforced plastics; automatic transmission friction components; beater-add gaskets; clutch facings; corrugated asbestos-cement sheet; extruded sealant tape; filler for acetylene cylinders; high-grade electrical paper; millboard; missile liner; roofing felt; and vinyl-asbestos floor tile. See Scope of the Risk Evaluation for Asbestos, Jun. 2017, pp. 24-25, available at: https://www.epa.gov/sites/production/files/2017-06/documents/asbestos_scope_06-22-17.pdf.

20	Healey_CommentAugust72018	1	Exposure	2.2
21	Healey_CommentAugust72018	1	Exposure	2.2

The vast majority of the asbestos currently in place in the U.S. is in the form of "legacy" materials. The relatively small amounts of new asbestos being introduced into the United States, as documented by EPA in the asbestos Problem Formulation pales in comparison to the amount of asbestos currently in place in buildings, vehicles, underground, and elsewhere. While only approximately 300 metric tons, or 661,387 pounds, of asbestos was imported into the U.S. in 2017, an amount of approximately 11,598 metric tons, or 25,568,292 pounds, of asbestos containing materials has been documented as having been disposed of as solid waste or otherwise released in the U.S. in 2015. These so-called "legacy" use materials continue to present very significant exposure risks, both in the asbestos abatement process and as a result of environmental releases from the disturbance of "legacy" materials that are not subject to the abatement process. For example, the cutting and beveling of asbestos cement pipe leads to extremely high airborne concentrations of asbestos fibers putting workers at risk.
EPA does not even attempt to provide a rationale for ignoring exposures related to the current widespread and most common uses of asbestos by excluding so-called "legacy" uses from its risk evaluations under Section 6 of TSCA. Rather than providing either legal or data-based justifications for its decision, the agency merely states: "EPA interprets the mandates under section 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on current and prospective uses for which manufacture, processing, or distribution in commerce is intended, known or reasonably foreseen, rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of "conditions of use" in that context (TSCA section 6(b)(4)(B)). In other words, EPA interprets the risk evaluation process of section 6 to focus on the continuing flow of chemical substances from manufacture, processing and distribution in commerce into the use and disposal stages of their life cycle. Consistent with this rationale, EPA has excluded certain uses from the scope of the risk evaluation, as identified below." [p. 20]

22	Healey_CommentAugust72018	1	Exposure	2.2
23	Anonymous1CommentAugust142018	1	General	N/A

Another “legacy” use not included in EPA’s Scope of the Risk Evaluation for Asbestos is the use of Libby Amphibole asbestos (which EPA describes as “a mixture of several mineral fibers such as winchite, richterite, and tremolite found in vermiculite ore near Libby, Montana). This notwithstanding that EPA readily admits Libby Amphibole has the potential for human exposure: "Although vermiculite contaminated with the Libby Amphibole remains in buildings as an insulating material and therefore presents the potential for human exposure, vermiculite containing the Libby Amphibole is no longer manufactured or processed for use in the United States and therefor is not considered a condition of asbestos use for the purpose of risk evaluation under TSCA.” Here, EPA is arbitrarily and capriciously limiting the uses that qualify as conditions of use to future applications, even while confirming the potential for human exposure as well as the risks to human health presented by such exposures.
Obviously this is a horrible idea even thinking that we should allow asbestos in anything. It’s not even close to a good idea. You’re the EPA. Clean air, clean water, clean everything and anything. Progress involves moving forward with cleaner solutions for everything. That involves moving away from things we know are harmful. Asbestos is one of those things. Please hold corporations and polluters more responsible. Thank you. [comment was downloaded from 1-BP docket}

24	UCSF_CommentJune252027	2	Exposure	2.2
25	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.2.2, 2.3.5

In the Introduction section of the chemical Scope documents [Section 1], EPA states that it "may consider background exposures from legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses." This falls short of the analysis required under Lautenberg TSCA. It is critical that EPA consider ongoing exposures from legacy uses and disposal, and includes these as part of the aggregate exposure assessment. Asbestos and HBCD are two examples of this, as they have enormous volumes in place in buildings and existing infrastructure. The Healthy Building Network estimates there are 66 million-132 million pounds (30,000-60,000 metric tons) of HBCD in insulation in existing buildings —these reservoirs in-place are and will continue to be critical sources of ongoing exposures. HBCD was also used in cars and furniture, which are long-lived consumer items that will continue to contribute to ongoing exposures for years to come.
1. Legacy Contamination In addition to the City's concern about EPA's decision to remove from the risk evaluation certain activities and exposure pathways discussed below, the City is also concerned with excluding legacy uses from Problem Formulations and risk analyses. [p. 8-9, 20-21 of PF for asbestos] Many of the 10 chemicals have been used extensively in New York City, and are part of our built environment. The risks of exposure from legacy uses and disposal of these substances is noteworthy and ongoing.

26	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.2.2, 2.3.5

Asbestos is the prime example of a dangerous substance that is still widely present in older building materials and infrastructure. Legacy asbestos can become airborne and dangerous when it is disturbed—for example, by maintenance work and repairs, renovation, demolition, or accident. Legacy use of asbestos is a particular concern for workers who may disturb building materials or other infrastructure that contains asbestos. For example, asbestos-cement pipes and fittings have been widely used in America; water supply workers, plumbers, and others performing maintenance on such pipes can suffer exposure to airborne asbestos fibers when such pipes are drilled or otherwise cut. Legacy asbestos materials are a significant concern in the City, where multiple City agencies—namely, the Department of Sanitation, the Department of Environmental Protection, and the Department of Health and Mental Hygiene—regulate asbestos use, disposal, and abatement. Additionally, by excluding all consideration of the risks of Libby Amphibole asbestos—a type of asbestos derived from minerals mined near Libby, Montana that is no longer used in new products—EPA is simply ignoring the ongoing risks from Libby Amphibole that "remains in buildings as an insulating material."[p. 21 of PF for asbestos]

27	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.2.2, 2.3.5
28	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.2.2, 2.3.5
29	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.2.2, 2.3.5

TSCA also does not adequately address legacy uses of PERC, methylene chloride, carbon tetrachloride, and TCE, as well as bystander exposure to PERC.17 These chemicals are possible or probable human carcinogens and toxic to various organs including the kidney and liver. They are very frequently found in groundwater and soil vapor throughout the City. This "legacy" directly impacts many New Yorkers due to widespread historic (and often current) use and the dense urban environment. These chemicals enter buildings through the soil vapor and frequently cause residents to breathe concentrations that are well above health-based guidance values. However, the extent of this problem is poorly studied and not adequately addressed byany federal acts. Because whole buildings or neighborhoods are sometimes affected, attempting to remediate these chemicals after they have entered into groundwater and soils is expensive and time consuming, and occurs only after building occupants, including children, are exposed to them. In order to prevent human health consequences, and an extraordinary waste of resources, TSCA must regulate them before they are legacy pollution.
By disregarding the risks of legacy uses of all 10 chemicals, most importantly asbestos, PERC, methylene chloride, carbon tetrachloride, and TCE, EPA is excluding from its consideration the means by which many Americans may be exposed to these hazardoussubstances, and undercounting the net risks of exposure for all Americans.
2. Unduly Narrow Scope In many other ways, EPA's Problem Formulation has an unduly narrow scope of consideration. For example, EPA is also excluding from consideration all uses of asbestos not specifically identified by EPA, since EPA considers the use of asbestos in such "unspecified activities" as "not reasonably foreseen in the United States." To the contrary, asbestos continues to make its way into a variety of unexpected products—for example, children's crayons sold in the United States recently tested positive for asbestos. Similarly, although the Problem Formulation acknowledges that New Jersey identifies talc-containing asbestos as a hazardous substance, EPA does not discuss the risks of asbestos in talc at all.

30	EPA-HQ-OPPT-2016-0737-DRAFT-0108_NYC	3	Exposure	2.6
31	EPA-HQ-OPPT-2016-0737-DRAFT-0110_NABTU	2	Exposure, Policy	2.2, 2.5

To avoid overlooking unforeseen uses of asbestos EPA should acknowledge that it remains in use, and that therefore risks associated with legacy use and pathways that do not relate to its manufacture or the conditions of use defined by EPA may remain. These risks must be assessed in the risk analysis for EPA's approach to be rational. In contrast, EPA simply excludes from its consideration all non-specified uses.
The Problem Formulation Documents show that EPA understands that a full risk assessment model includes considerations of all the uses, pathways, and routes that pose the greatest risk of injury to the health of potential "receptors." See, e.g., Figures 2-2, 2-3, and 2-4 of each Problem Formulation Document. The agency, however, has decided to exclude from its risk assessment certain aspects of the chemicals' life cycles that are particularly important sources of exposure for construction workers. For example, as NABTU has described in detail in its comments on the Problem Formulation Document for Asbestos, excluding from "conditions of use" any "legacy uses" of the priority chemicals will eliminate evaluation of significant sources of exposure for construction workers. See NABTU comments submitted under EPA-HQ-OPPT-2016-0736. In addition, EPA must evaluate exposures from known and reasonably foreseeable "conditions of use" in addition to intended uses. EPA has decided not to evaluate exposures from many commercial uses of various chemicals stating that the products are not advertised for consumers. See e.g., Problem Formulation Document for 1-BP at 19. However, despite how a product is advertised, it may be used by consumers, particularly small contractors. This is an important source of exposure as businesses with one to nine employees made up 81% of the construction industry in 2012.

32	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Exposure	2.2, 2.3
33	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Exposure, Human Health	2.3, 2.4
34	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General	N/A

• Despite the deep concerns of commenters, the problem formulations reaffirm EPA's exclusion from its risk evaluations of ongoing use and disposal of chemical products that are no longer being manufactured (so-called "legacy uses"). This use and disposal clearly falls within the TSCA definition of "conditions of use" and its exclusion violates the plain language of the law. As the case of asbestos illustrates, discontinued products may be ubiquitous in the built environment and their contribution to current and future exposure and risk may greatly dwarf that of the few products that remain in commerce. To ignore this source of risk would deprive the public, scientists and regulators of important information about threats to public health and prevent policymakers from taking meaningful action to protect at-risk populations. (Section V, pages 14-16)
• As the asbestos risk evaluation illustrates, EPA has also dropped from consideration significant health end-points known to be linked to exposure to the chemical. This omission is likewise contrary to TSCA's comprehensive approach to evaluating risk. (Section IX, pages 24-25)
• Six of the 10 chemicals – asbestos (and Libby amphibole asbestos), trichloroethylene (TCE), methylene chloride (MC), carbon tetrachloride (CTA), perchloroethylene (PERC) and 1,4-dioxane – have been assessed under the EPA Integrated Risk Information System (IRIS). The IRIS process is the Agency's authoritative mechanism for reviewing available studies and characterizing the health effects of chemicals. The problem formulations, however, indicate that EPA will revisit the interpretation of studies already evaluated in IRIS using its highly questionable TSCA "systematic review" method that has not been peer reviewed. This may lead to departures from IRIS determinations of the "best available science" and "weight of the evidence." Reopening IRIS findings would harm the public by prolonging uncertainty on issues that have been addressed and resolved through an authoritative and transparent process. In rare cases where significant new data (since the IRIS assessment) are available, the EPA TSCA program should rely on the IRIS program to review, assess, and if appropriate incorporate any new information using a systematic review method that is consistent with the state of the science. (Section X, pages 25-28)

35	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure	Executive Summary
36	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	Exposure, Human Health	2.2, 2.3

V. Ongoing Use and Disposal of Chemical Products that are No Longer Being Manufactured Fall Within the TSCA Definition of "Conditions of Use" and Cannot Be Excluded from Risk Evaluations Among the 10 chemicals are substances, such as asbestos and HBCD, that contribute to ongoing exposure and risk as a result of historical manufacturing and processing activities that have been discontinued. In many cases, the current and foreseeable risks associated with these activities are significant. Nonetheless, the problem formulations, like the scoping documents, take the position that they are outside the scope of risk evaluations. As stated in EPA'S asbestos problem formulation: "In the case of asbestos, legacy uses, associated disposals, and legacy disposals will be excluded from the problem formulation and risk evaluation, as they were in the Scope document. These include asbestos containing materials that remain in older buildings or are part of older products but for which manufacture, processing and distribution in commerce are not currently intended, known or reasonably foreseen. EPA is excluding these activities because EPA generally interprets the mandates under section TSCA § 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacture, processing or distribution is intended, known to be occurring, or reasonably foreseen, rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of conditions of use in that context."
For example, although asbestos may no longer be sold as insulation, the asbestos insulation installed in millions of US buildings continues to perform insulating functions and thus is a current ongoing "use" of asbestos. Installed asbestos-containing building materials (ACBMs) represent one of the largest sources of asbestos accessible to the general public in the US, and the largest asbestos-exposed population consists of people who occupy buildings and homes with ACBMs. Maintenance and construction activities involving ACBMs are also frequent and widespread and account for the largest present-day increase in mesothelioma illness and death in the US.

37	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Exposure	2.2, 2.3
38	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy, Exposure	2.2, 2.3

To exclude from risk evaluations ongoing and future exposures from in situ uses of discontinued products would create a sizable gap in the life-cycle assessments of risk that Congress directed EPA to conduct under the new law. This would deprive the public, scientists and regulators of a comprehensive picture of one of the largest sources of continuing and future risk. Since in situ sources of exposure form a critical component of the background levels of asbestos and other chemicals to which the general population is exposed, EPA's assessment of risks to particular subpopulations from more specific exposure pathways would also be incomplete and understated.
In addition, decision-makers would be unable to reduce ongoing exposures and impose safeguards against unsafe use and disposal and "legacy" products because they would lack a meaningful risk evaluation to inform these actions. Just as TSCA provides authority to evaluate the risks associated with ongoing exposures from discontinued activities, so it gives EPA the authority under section 6(a) to reduce these risks, yet the Agency would be stymied by the absence of a risk evaluation that provides a basis for such regulation.31 Footnote: 31 For some chemicals like lead and asbestos, other laws administered by EPA address handling and disposal of in situ materials and the Agency may be able to refer the findings of its risk evaluations to the programs implementing these laws under TSCA section 9(b) in lieu of further regulation under section 6. However, there are no existing laws that address ongoing exposure from use and disposal of discontinued products containing HBCD, perfluorinated chemicals and other substances and therefore the availability of the protections afforded under section 6 of TSCA may be critical to addressing their risks. Obviously, if these risks are not identified and evaluated under TSCA section 6(b), there will be no basis for reduction them through regulation under section 6(a).

39	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Epolicy	2.2
40	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Human Health	N/A, 2.4.2

EPA has also narrowed the scope of the asbestos risk evaluation by excluding now discontinued but historically significant asbestos-containing products and failing to address mining of asbestos in the US. Instead, EPA has proposed a significant new use rule (SNUR) so that it is notified of the reintroduction of discontinued products before it occurs. However, while EPA has the ability to ban or restrict a new use after receiving notification under a SNUR, the SNUR does not itself comprise a finding of unreasonable risk nor does it provide any assurance that the use would be regulated once the Agency receives a significant new use notice (SNUN). With the exclusion of discontinued asbestos uses, the EPA risk evaluation will be limited to the small number of asbestos products that remain in commerce, providing a grossly incomplete picture of the threat to health from past and potential future uses of asbestos.
IX. EPA Cannot Drop Significant Hazards from Risk Evaluations The asbestos problem formulation provides another example of an EPA decision “not to further analyze” a potential source of risk. EPA has chosen to limit its asbestos evaluation to lung cancer and mesothelioma. Yet the asbestos scoping document is clear that several other cancers have been linked to asbestos: "Mortality studies of asbestos workers have revealed increases in cancer mortality at one or more sites other than the lung, the pleura or the peritoneum. Cancer of the larynx and ovary and gastrointestinal cancers, such as colorectal, pharynx and stomach, have been observed in populations exposed to various types of asbestos (IARC, 2012; NRC, 2006). Some studies have also noted excess deaths from, or reported cases of, cancers at other sites, such as the kidney and esophagus; however, the evidence is not consistent." Non-malignant diseases are also caused by asbestos, including asbestosis and asbestos-related pleural thickening.

41	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A
42	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy, Systematic Review	N/A

X. EPA Should Not Revisit Definitive Findings in IRIS Assessments Unless There Are New Data That Inform EPA's Evaluation of the Weight of the Evidence

Six of the 10 chemicals -- asbestos, TCE, MC, CTC, PERC and 1,4-dioxane -- have been assessed under the EPA Integrated Risk Information System (IRIS). The IRIS process is the Agency's authoritative mechanism for reviewing available studies, characterizing the health effects of chemicals and identifying concentrations below which these chemicals are not likely to cause adverse effects. IRIS assessments typically reflect years of work by EPA scientists, multiple rounds of public comment, inter and intraagency consultation, and extensive peer review, often by the Agency's independent Science Advisory Board (SAB) or the National Academy of Sciences (NAS). The IRIS program recently received a favorable review from the NAS.

In the problem formulations themselves, however, EPA outlines a much broader approach. It indicates that all studies on IRIS-assessed chemicals will be reviewed using the "study quality" scoring system in EPA's TSCA systematic review document and other as-yet unidentified protocols for reviewing study relevance and weight.61 This process would necessarily involve revisiting the interpretation of studies already evaluated in IRIS, potentially making different judgments about their quality and relevance and modifying overall IRIS determinations of the "best available science" and "weight of the evidence." Moreover, these judgments would be driven by a deeply flawed and unscientific method for reviewing studies that would result in less defensible conclusions than peer reviewed IRIS assessments.

Footnote:

61 Typical is this description of EPA's approach in the problem formulation for asbestos, the subject of a comprehensive IRIS assessment:

EPA expects to consider and analyze human health hazards as follows:

1) Included human health studies will be reviewed using the evaluation strategies laid out in the Application of Systematic Review in TSCA Risk Evaluations (U.S. EPA, 2018).

- Studies will be evaluated using specific data evaluation criteria.
- Study results will be extracted and presented in evidence tables by cancer endpoint.

2) Evaluate the weight of the scientific evidence of human health hazard data.

- EPA will rely on the weight of the scientific evidence when evaluating and integrating human health hazard data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.
- Assess dose-response information to refine quantitative unit risk for lung cancer and mesothelioma. Review the appropriate human data identified to update, or reaffirm, the 1988 quantitative estimate of the unit risk of asbestos-related lung cancer and mesothelioma by the inhalation route.

3) In evaluating reasonably available data, EPA will determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.

43	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A

The drawbacks of reopening IRIS assessments are particularly troubling in the case of asbestos. The problem formulation indicates that EPA will review the asbestos database "with the goal of updating, or reaffirming, the unit risk." 63 It describes this review as follows: "Asbestos has an existing EPA IRIS Assessment and an ATSDR Toxicological Profile; hence, many of the hazards of asbestos have been previously compiled and reviewed. EPA relied heavily on these comprehensive reviews in preparing the scope and problem formulation documents. EPA expects to use these documents as a starting point for identifying key and supporting studies to inform the human health hazard assessment, including dose-response analysis. EPA also expects to consider other studies that have been published since these reviews, as identified in the literature search conducted by the Agency for asbestos (Asbestos (CASRN 1332-21-4) Bibliography: Supplemental File for the TSCA Scope Document, EPA-HQ-OPPT-2016-0736). . . . The relevant studies will be evaluated using the data quality criteria in the Application of Systemic Review in TSCA Risk Evaluations document (U.S. EPA, 2018)."

44	EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, Policy	N/A

There is no benefit – and considerable downside – in reconsidering the unit risk estimates provided by the IRIS program for asbestos of all fiber types (IRIS 1988) and Libby amphibole asbestos (IRIS 2014). The highly flawed TSCA systematic review method for determining study "quality" would make it difficult for EPA to include important human health and toxicology studies in its chemical hazard assessments if there is any information that is missing or not publicly available. Rejecting or downgrading epidemiological studies on asbestos on this ground could lead EPA to develop a new risk estimate that adopts the asbestos-industry position that chrysotile is safe – a position that was proposed by EPA under the George W. Bush Administration, but rejected by the Scientific Advisory Board, which specifically warned that failure to consider epidemiology and toxicology data for asbestos is problematic.68 These errors and scientific omissions could be repeated if application of the TSCA systematic review criteria results in discarding much of the asbestos epidemiology evidence.69 This would be a huge step back from the settled scientific consensus on the severe dangers of asbestos to public health.

Footnotes:

68 SAB consultation on EPA's Proposed Approach for Estimation of Bin-Specific Cancer Potency Factors for Inhalation Exposure to Asbestos. Nov, 2008. EPA-SAB-09-004.
https://yosemite.epa.gov/sab/sabproduct.nsf/77CFF6439C00ABF3852575010077801F/$File/EPA-SAB-09-004-unsigned.pdf

69 See for example Table H-8 of the draft systematic review guidance which lists several pages of "serious flaws that would make epidemiological studies unacceptable for use," including failure to report various sorts of information, which is not considered a measure of study quality by any other peer reviewed systematic review framework.

EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Exposure	2.3
EPA-HQ-OPPT-2016-0737-DRAFT-0114_SCHF	1	General, RegNex, Exposure	2.2, 2.3

Second, a number of the OSHA standards that apply to chemicals subject to the first 10 risk evaluations were developed many years ago and do not reflect current data and scientific understanding of the health effects of the regulated chemicals.81 Thus, the levels of exposure allowed by these standards may be unsafe when evaluated using the best available science. Footnote: 81 OSHA has two types of standards. Under section 6(a) of the OSH Act, OSHA adopted hundreds of PELs in 1971 that were, at that time, considered national consensus standards. They have not been updated since and are based on science from the 1960s or earlier. Since 1971, OSHA has regulated only about 40 chemicals under section 6(b). These more comprehensive standards are based on thorough evaluation of health effects and a determination that risks are significant. OSHA has 6(b) standards regulating only asbestos and MC. It has PELs (adopted under 6(a)) for PERC and TCE but not for the other 10 chemicals. In the case of both asbestos and MC, OSHA's published Federal Register preambles found that even at the revised PEL, employees continued to be exposed to significant risks i.e., risks above 1/1000 – OSHA's definition of significant risk.
Third, OSHA does not cover all workers. It only covers private sector employees of employers. It does not cover employees of federal, state or local governments. These workers might include building maintenance people exposed to asbestos, hospital workers exposed to PERC when laundering linens or other supplies, etc. OSHA also does not cover independent contractors. In the construction sector, many people performing remodeling work, such as stripping paint and otherwise using MC, or removing asbestos insulation are independent. These workers have no OSHA protection. So even if OSHA standards were adequately protective of the workers they covered, there would still be a need for EPA to act under TSCA to make sure all workers had an equivalent level of protection.